

HIGHLY CONFIDENTIAL (TECHNICAL) - ATTORNEYS' EYES ONLY

**IN THE UNITED STATES DISTRICT COURT**

**FOR THE DISTRICT OF DELAWARE**

CYTIVA SWEDEN AB and GLOBAL LIFE	)	
SCIENCES SOLUTIONS USA LLC,	)	
	)	
	)	
	)	C.A. No. 18-1899-CFC
Plaintiffs,	)	Consolidated
	)	
v.	)	Redacted: Public Version
	)	
BIO-RAD LABORATORIES, INC.,	)	
	)	
Defendant.	)	

**DECLARATION OF STEVEN WERELEY, PH.D.**

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f.	a fluidics section; .....	198
g.	a non fluidics section in turn comprising electronics or electrical components or control means; and .....	198
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**I. INTRODUCTION**

1. The following is a brief summary of my background and qualifications, which are more fully set forth in my curriculum vitae, attached as Exhibit A.

2. I have two Bachelor degrees, a Bachelor of Arts in Physics from Lawrence University, awarded in 1990, and a Bachelor of Science in Mechanical Engineering from Washington University in St. Louis, also awarded in 1990. The two degrees were awarded in the same year because I pursued a cooperative program where the classes from each university satisfied the requirements of the other university. I received my Master of Science in 1992 and Doctor of Philosophy in 1997, both from the Northwestern University Department of Mechanical Engineering. While pursuing my MS and PhD, I specialized in fluid mechanics, the study of how fluids move. After completing these degrees, I performed a post-doctoral research appointment at the University of California Santa Barbara in the Department of Mechanical and Environmental Engineering from 1997 until 1999. During my time at the University of California Santa Barbara I specialized in the study of microfluidics—the study of how fluids move in very small systems.

3. I am currently and have been an employee of the Purdue University School of Mechanical Engineering since August 1999. I was hired as an Assistant

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Professor, promoted to Associate Professor in 2006 and subsequently to Professor in 2010. I have been invited to serve as a visiting professor at three different universities, Technische Universität Darmstadt (Darmstadt, Germany), Universität der Bundeswehr (Munich, Germany) and Royal Melbourne Institute of Technology (Melbourne, Australia). These visits were partially paid for by the hosting universities. I hold the rank of Fellow in both the American Society of Mechanical Engineers (ASME) and the American Physical Society (APS). Fellow status in the American Physical Society is an honor that is bestowed upon only 0.5% of APS membership.

4. I have engaged in many research projects in the field of fluid mechanics, resulting a long list of publications featuring two co-authored textbooks, 14 book chapters, 83 peer-reviewed journal articles, nearly 200 conference papers and presentations and nine co-authored patents. I have delivered invited lectures all over the world. Some of these invited lectures have been at large international scientific meetings such as The Gordon Research Conference on Plasmonics and Nanophotonics (2016, Newry, ME), the Chinese Society for Micro and Nano Technologies (2016, Beijing, China), International Society for Photonics and Electronics (2015, San Diego, CA), World Conference on Experimental Heat

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Transfer, Fluid Mechanics and Thermodynamics (2015, Lisbon, Portugal), International Conference on Nanochannels, Microchannels, and Minichannels (2012, Puerto Rico, USA), International Conference on Fluid Mechanics and Fluid Power (2006, Mumbai, India), among many others.

5. Much of my research throughout my career has been in the field of automated fluid handling systems. Topics include using light and electric fields to control fluid and particle motion (e.g. “Light-actuated electrothermal microfluidic flow for micro-mixing,” published in Journal of Micromechanics and Microengineering, 2018), using arrays of valves to move fluid samples through fluidic networks (e.g. “On-chip dilution in nanoliter droplets,” Analyst, 2015), and using light to control droplets’ motions (e.g. “Open Optoelectrowetting Droplet Actuation,” Applied Physics Letters, 2008). All the way back to my PhD work in 1997, I was building automated fluid handling systems. In the case of my PhD work, I designed a system with pumps and valves for the purpose of evaluating rotating filtration systems of the type used for separating cellular components from whole blood. Many of my patents are in the automated fluid handling area. These include “System and method for manipulation of particles,” US Patent 9,778,400 (2017); “Hybrid device for on-chip concentration, manipulation, sorting and sensing of

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particles on a plasmonic substrate,” US Patent 9,443,632 (2016); “Variable volume mixing and automatic fluid management for programmable microfluids,” US Patent 9,211,539 (2015); and “Microfluidic Purge Valve,” US Patent 8,376,317 (2013); among others.

6. From approximately 2009 I co-founded the company Microfluidics Innovations, LLC. Microfluidics Innovations specialized in designing and manufacturing automated liquid handling systems. The company was founded based on intellectual property developed during research from approximately the 5 years predating its founding. As a co-founder of the company my role was primarily that of scientific advisor in the fluid handling area. As such I was involved in many projects adapting Microfluidics Innovations products to customers’ needs

## **II. ASSIGNMENT**

7. Counsel for Cytiva Sweden AB and Global Life Sciences Solutions USA LLC. (which I will refer to herein as “Cytiva”) have engaged me in this case. I have been compensated at a rate of \$600 per hour for my consulting work. My compensation is not contingent upon the outcome of this case. I am submitting this declaration at the request of Cytiva.



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8. In formulating the opinions contained in this declaration, I have considered my training, knowledge, fundamental engineering principles, scientific principles, and experience in the relevant scientific disciplines, as well as the materials cited herein. In addition to the conclusions and opinions set forth in this declaration, my testimony may include responses to facts, arguments, allegations, or references raised by Defendants or their experts relating to this litigation.

9. If asked, I will be prepared to present a basic tutorial to explain the terms and concepts related to the opinions set forth in my declaration, as well as to provide further background on liquid chromatography, the state of the art, the level of skill in the art, and the patents at issue. That tutorial may include demonstrative exhibits and exemplary liquid chromatography systems. In addition to the opinions and bases set forth in this declaration.

### **III. RELEVANT LEGAL PRINCIPALS**

10. Although I am not an attorney and will not offer legal opinions, in preparation for forming the opinions set forth in this declaration I have been informed regarding the relevant legal principles. I have used my understanding of those principles in forming the opinions set forth herein. My understanding of those principles is summarized below.

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**A. Burden Of Proof**

11. I understand that Cytiva has the burden of proving infringement by a preponderance of the evidence. I understand that the “preponderance of the evidence” standard requires that the patentee present evidence which, considered in the light of all the facts, shows that the allegations of infringement are more likely true than not

**B. Infringement**

**1. Direct Infringement**

12. As set forth above, I understand that the infringement analysis comprises two steps, and that the first step is determining the proper construction of the Asserted Claims. I understand that the second step of the infringement analysis is determining whether an accused product contains or practices each claim element/limitation or its equivalent.

13. I understand that there are two types of direct infringement: “literal” infringement and infringement under the “doctrine of equivalents.”

14. I understand that, in order for a patent claim to be literally infringed, each and every element/limitation of the claim must be present, as claimed, in the accused product. In order for a method patent claim to be literally infringed, someone

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must perform each step, as claimed. It is also my understanding that the failure to meet even a single claim element or limitation is sufficient to show that the accused product does not literally infringe the asserted claim.

15. I understand that one cannot avoid infringement merely by adding elements if each element or limitation recited in the claims is found in the accused product or method.

16. I understand that a claim in dependent form includes all the limitations of the claim(s) from which it depends.

17. I have been informed that Cytiva is not asserting infringement under the doctrine of equivalents, so I will not discuss it.

**2. Indirect Infringement**

18. I understand that one can be held liable for active inducement of patent infringement by inducing the completion of all steps or elements of a patent claim with knowledge that such acts constitute patent infringement. I further understand that one can also be held liable for offering to sell or selling within the United States or importing into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to

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be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

#### IV. THE PATENTS IN SUIT

19. This litigation involves United States Patent Nos. 9,709,589 (“the ’589 Patent”) (Ex. 32), 9,709,590 (“the ’590 Patent”) (Ex. 33), 9,709,591 (“the ’591 Patent”) (Ex. 34), 9,671,420 (“the ’420 Patent”) (Ex. 35), and RE47,124 (“the ’124 Patent”) (Ex. 36) (collectively, the “Asserted Patents”). In this declaration, will address infringement of certain claims of the ’420, ’589, ’591 and ’124 patents.

20. The Asserted Patents disclose and claim novel automated liquid chromatography embodiments. The Asserted Patents each state that:

The present invention relates to the art of fluid handling system systems, and in particular to an automated fluid handling system that is highly flexible and configurable. The fluid handling system may e.g. be a liquid chromatography system, a filtration system, a chemical synthesis system or the like.

the ’589 Patent, 1:22-27.<sup>1</sup> The Asserted Patents also state:

The object of the invention is to provide a new fluid handling system, which system overcomes one or more

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<sup>1</sup> Unless I state otherwise, all citations to the Asserted Patents are from the ’589 Patent.

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drawbacks of the prior art. This is achieved by the fluid handling system as defined in the independent claims.

One advantage with such a fluid handling systems is that the system may easily be upgraded without need for add-on equipment, and that the flow path may be easily optimized for new experimental setups.

*Id.*, 1:50-59.

21. The Asserted Patents state that one embodiment of the invention as follows:

FIG. 1 shows one embodiment of an automated fluid handling system modular in the form of a liquid chromatography system, with a plurality of interchangeable modular components arranged in a liquid handling panel wherein the reference numbers denotes:

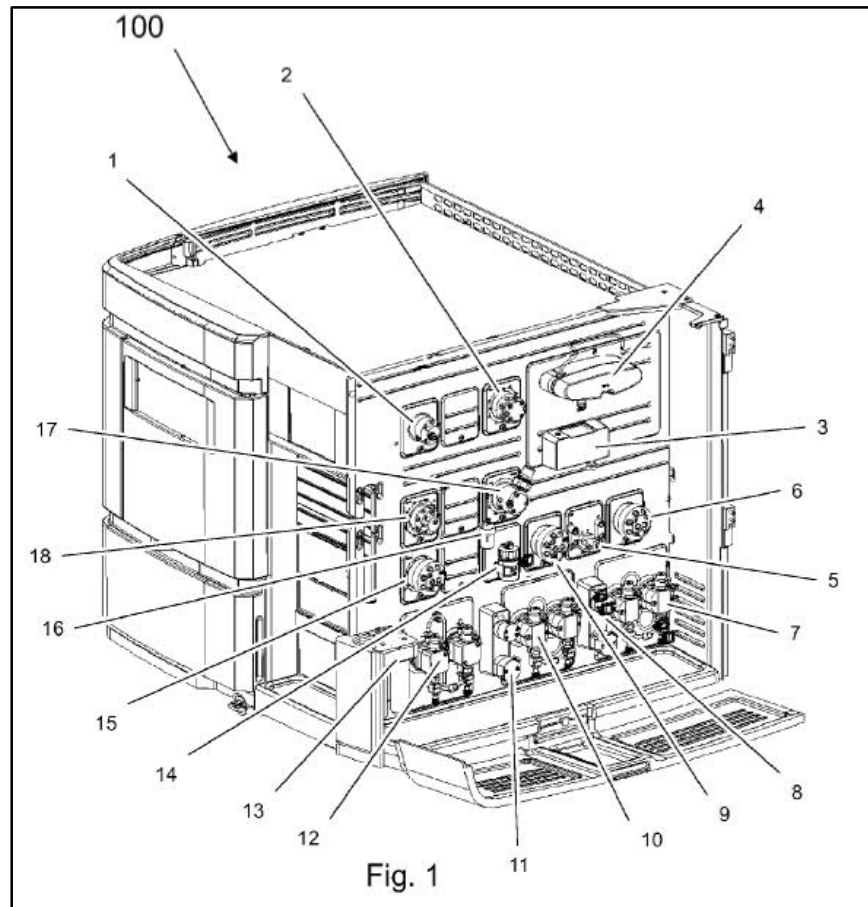
1. Injection valve
2. Column valve with integrated pressure sensors
3. Conductivity monitor
4. UV monitor
5. Quaternary valve
6. Inlet valve B with integrated air sensor
7. System pump
8. Pressure monitor, system pump
9. Inlet valve A with integrated air sensor

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10. System pump
11. Pressure monitor, sample pump
12. Sample pump
13. Rinsing system
14. Mixer with online filter
15. Sample inlet valve with integrated air sensor
16. Flow restrictor
17. pH valve
18. Outlet valve

*Id.*, 2:50-3:5. For convenience, Fig. 1 is reproduced below, where placement of the above-identified modules are arranged in a liquid handling panel of the system:

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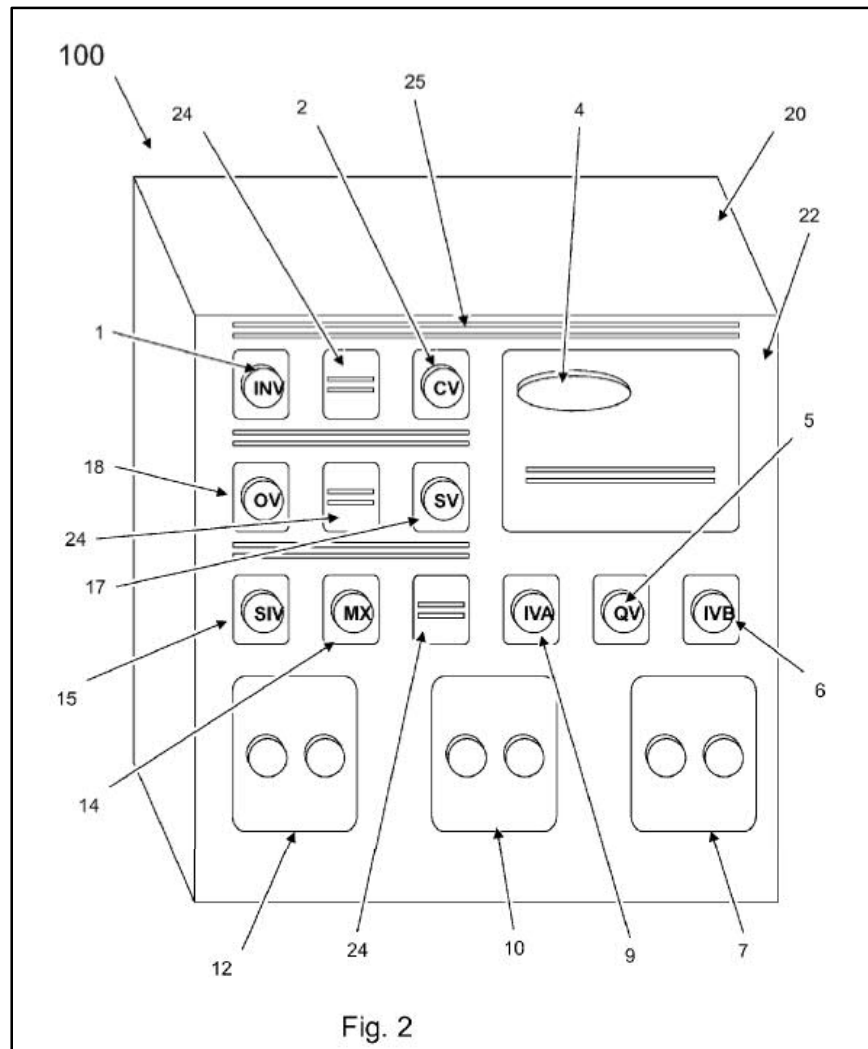


22. Exemplary modules, which the patent refers to as “interchangeable modular components” (and other terms), include injection valve 1, column valve 2, UV monitor 4, system pumps 7 and 10, inlet valve 6 and 9, sample inlet valve, pH valve 17, and outlet valve 18.

23. Fig. 2 of the Asserted Patents “is a schematic illustration of a housing 20 with a liquid handling panel 22 of the fluid handling system in the form of a

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modular liquid chromatography system 100 of FIG. 1. ■ *Id.*, 5:38-41. I have reproduced Fig. 2 below:



24. Liquid handling panel 22 is located on one side of housing 20, and defines a number of openings, which the Asserted Patents often call “locations.” The various modules are inserted into these locations. The specification further states:



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In the disclosed configuration, as disclosed in detail above, the modular liquid chromatography system 100 comprises a plurality of fluid control valves in the form of: Injection valve 1, Column valve 2, Quaternary valve 5, Inlet valve B 6, Inlet valve A 9, Sample inlet valve 15, pH valve 17, and Outlet valve 18. The chromatography system 100 further comprises UV monitor 4, System pump B 7, System pump A 10, Sample pump 12, Mixer 14, and three Dummy modules 24.

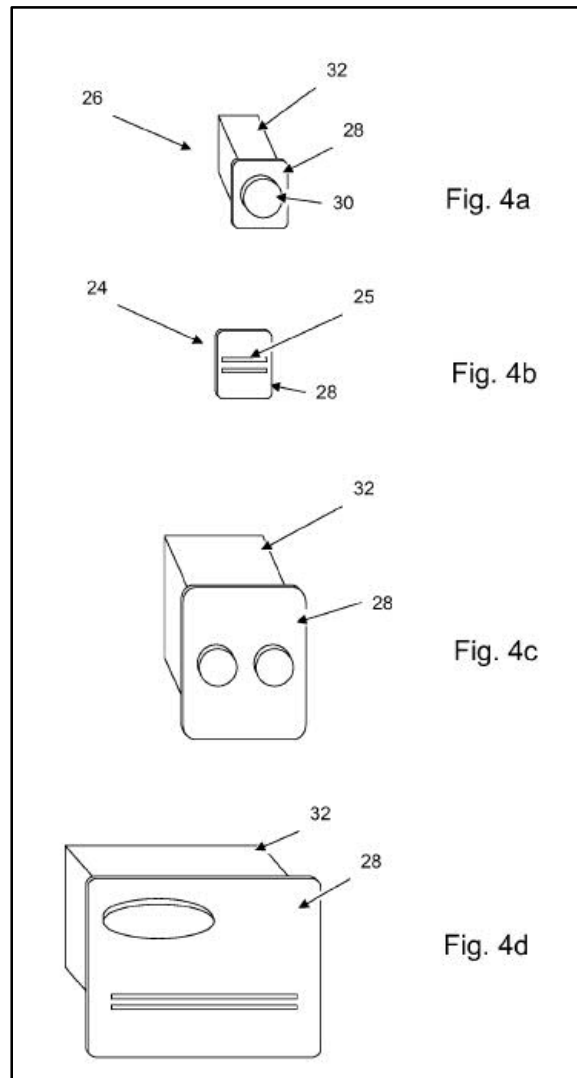
*Id.*, 5:41-50.

25. Another discussion the Asserted Patents have regarding modules is in the context of Fig. 4:

FIGS. 4a to 4d are schematic illustrations of examples of fluid handling units in the form of modular component of the fluid handling system removed. FIG. 4a shows a standard interchangeable modular component 26, e.g. a fluid control valve or the like. The standard component module 26 comprises a panel member 28, an external fluidics section 30 and an internal non-fluidics section 32. According to one embodiment, the panel member 28 essentially separates the fluidics in the external fluidics section 30 from electronics and control means in the internal non-fluidics section 32.

*Id.*, 6:4-13. I have reproduced Figs. 4a-4d below:

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26. Except for the “dummy module” shown in Fig. 4b, each of the modules depicted in Figs. 4a-4b and 4d are made up of several members, or sections. A first is panel member 28. A second is non-fluidics section 32 and a third is fluidics section 30. Of course, a person of ordinary skill in the art (“POSITA”) would understand that there could more sections than just these. Indeed, the Asserted

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Patents refer to various sensors that are externally located, e.g., pH electrodes. Such sensors are electrochemical in nature and are located outside of the interior of the modules and housing.

27. The Asserted Patents call out certain features that a POSITA would have realized were important advancements in liquid chromatography technology. One important advancement was providing users with the ability to easily modify their systems so that they could optimize the fluid flow paths of liquid chromatography runs:

To fulfill a desired purpose, with the disclosed liquid chromatography system it is possible to adapt and extend the flow path in a simple and a flexible way.

*Id.*, 4:65-67. The Asserted Patents further stress this advancement:

According to one embodiment, all liquid handling components and sensors arranged at the liquid handling panel 22 are designed to be readily interchangeable. The interchangeability provides improved service and upgrade possibilities and also a possibility to customize the positions of the respective liquid handling components, such as the fluid control valves, e.g. in order to optimize the fluid path for a specific experimental setup.

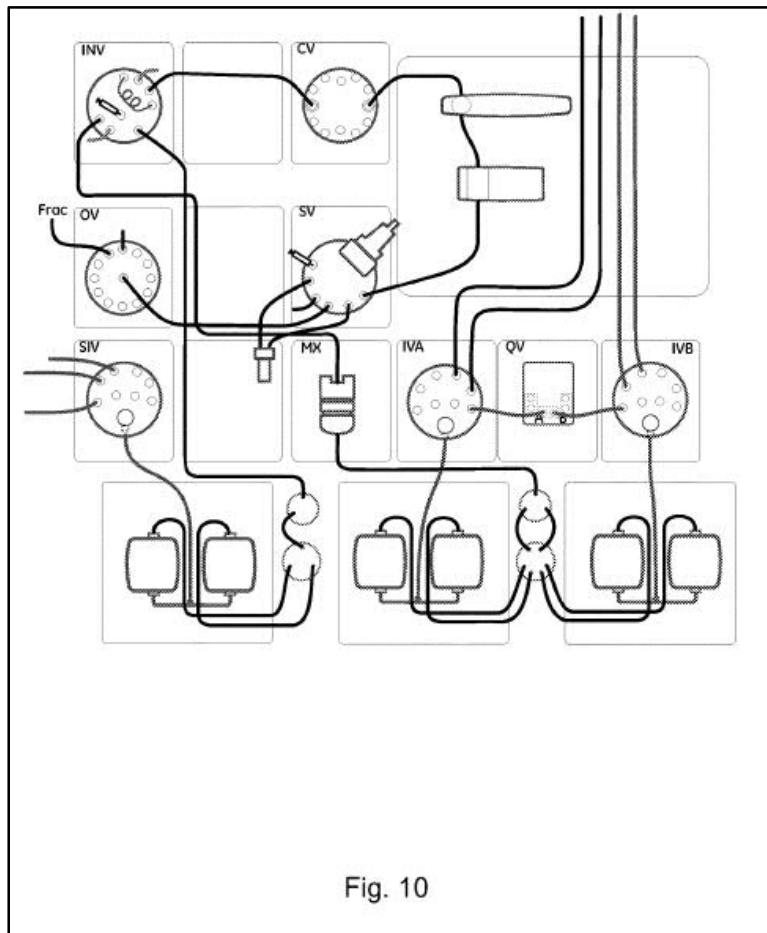
*Id.*, 5:50-57. The Asserted Patents provide further discussion regarding this important advancement in the context of Fig. 10:

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FIG. 10 is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel. Taking into account the complexity of the disclosed interconnection arrangement, the benefit of optimizing the fluid paths in alternative configurations of the system becomes evident. The task of optimizing the fluid paths may e.g. be performed to reduce the total length/volume of the fluid paths/tubing arranged to interconnect the different component modules in the system. Alternatively the optimization may be performed to minimize the length/volume of one or more specific fluid paths, such as the sample output path from the column to the fraction collector, in order to minimize dispersion of the fractionized sample.

*Id.*, 8:61-9:7. I have reproduced Fig. 10 below:

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28. Another important aspect of the inventions in the Asserted Patents is the separation of a fluidics section of the modules from the electronics in an internal non-fluidics section:

FIGS. 4a to 4d are schematic illustrations of examples of fluid handling units in the form of modular component of the fluid handling system removed. FIG. 4a shows a standard interchangeable modular component 26, e.g. a fluid control valve or the like. The standard component module 26 comprises a panel member 28, an external fluidics section 30 and an internal non-fluidics section

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32. According to one embodiment, the panel member 28 essentially separates the fluidics in the external fluidics section 30 from electronics and control means in the internal non-fluidics section 32.

*Id.*, 6:4-13. The Asserted Patents essentially repeat this important advancement, when stating:

As is disclosed in FIGS. 4a to 4d, the interchangeable modular components 26 comprises a panel member arranged to separate the fluidics section from the non fluidics section and for attachment to a component position in the liquid handling panel. Said panel attachment member may be arranged so that all fluid connections of said modular component are arranged on a wet side of the panel attachment member separating them from electrical components that are arranged on a dry side thereof, hence providing a high degree of liquid resistance at the external part of the fluid handling panel, and so that the liquid resistance requirements for the internal sections may be somewhat lightened.

*Id.*, 6:23-35.

29. I will discuss this in more detail below when addressing Bio-Rad's infringement of the Asserted Claims. However, I note initially that the specification discloses multiple examples of modules that have electrical components in locations other than the non-fluidics sections of the modules.

30. For example, above, I quoted a list of modules the Asserted Patents specifically identify, and a POSITA would understand that many of these can have

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electrical components located in areas outside any non-fluidics section. Such modules could include:

2. Column valve with integrated pressure sensors
3. Conductivity monitor
4. UV monitor
6. Inlet valve B with integrated air sensor
9. Inlet valve A with integrated air sensor
15. Sample inlet valve with integrated air sensor
17. pH valve
31. The Asserted Patents further disclose having each module have its own

CPU:

In one embodiment, each modular component is provided with a dedicated CPU unit allowing the component to independently perform operations in response to instructions over the BUS 42.

8:9-12.

32. Cytiva uses the inventions claimed in the Asserted Patents in its ÄKTA avant and ÄKTA pure automated liquid chromatography systems.

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**A. The '420 Patent**

33. The '420 Patent was filed on September 9, 2016 as a Continuation of U.S. patent application Ser. No. 15/165,876 filed May 26, 2016 which is a Continuation of U.S. patent application No. 14/463,039 filed Aug. 19, 2014 (now U.S. Pat. No. 9,404,902) which is a Continuation of U.S. patent application No. 13/376,929 (now U.S. Pat. No. 8,821,718) filed Dec. 8, 2011 which was a National Phase of the PCT application I mentioned above. It also claims priority to the Swedish patent application, filed Jun. 9, 2009, I discussed above.

**B. The '589 Patent**

34. The '589 Patent was filed on May 26, 2016 as a Continuation of U.S. patent application No. 14/463,039 filed Aug. 19, 2014 which is a Continuation of U.S. patent application No. 13/376,929 (now U.S. Pat. No. 8,821,718) filed Dec. 8, 2011 which was a National Phase of the PCT application I mentioned above. It also claims priority to the Swedish patent application, filed Jun. 9, 2009, I discussed above.

**C. The '591 Patent**

35. The '591 Patent was filed on July 8, 2016 as a Divisional of U.S. patent application No. 15/165,876, filed May 26, 2016 which is a Continuation of U.S.



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patent application No. 14/463,039 filed Aug. 19, 2014 which is a Continuation of U.S. patent application No. 13/376,929 (now U.S. Pat. No. 8,821,718) filed Dec. 8, 2011 which was a National Phase of the PCT application I mentioned above. It also claims priority to the Swedish patent application, filed Jun. 9, 2009, I discussed above.

**D. The '124 Patent**

36. The '124 Patent is a reissued version of U.S. Patent No. 8,821,718 (the "'718 Patent"). The '718 Patent was filed on December 8, 2011 (and assigned U.S. patent application No. 13/376,929, which was a National Phase of the PCT application I mentioned above. It also claims priority to the Swedish patent application, filed Jun. 9, 2009, I discussed above.

**V. THE PERSON OF ORDINARY SKILL IN THE ART**

37. I have been asked to provide a definition of "a person of ordinary skill in the art" ("POSITA") to whom the inventions disclosed and claimed in the patents-in-suit were directed, as of the relevant priority dates

38. For purposes of this declaration, I have been asked to assume that the priority date for each of the Asserted Patents is June 9, 2009, which is the date the Swedish priority application was filed. I note that my opinion regarding the

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definition of a POSITA would not change should the Court or other decision maker determine that that priority date is June 4, 2010, the filing date of the PCT application I mentioned above.

39. I have been informed that factors for determining ordinary skill in the art may include one or more of the following: (1) the educational level of the inventors; (2) the type of problems encountered in the art; (3) prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the relevant technology; and (6) the educational level of workers active in the field. I have considered these factors in my analysis.

40. For example, I note that one of the inventors of the Asserted Patents, Mats Lundkvist, has a bachelor's degree in Mechanical Engineering. Lundkvist 10/22/2014 Tr. 42:15-44:8.

41. In my opinion, a POSITA would have a scientific or technical background with at least 5 years of experience in the design, service, operation, and/or use of automated fluid handling systems, which would include liquid chromatography systems, filtration systems, chemical synthesis systems or the like.

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## VI. CLAIM CONSTRUCTION

42. I am informed that the Parties agreed to the following claim constructions:

Claim Term(s)	Agreed Upon Construction
“CPU” / “CPU unit”	“central processing unit”
“the fluidics section is external to the housing and the non[-]fluidics section is internal to the housing”	“the fluidics section is on the outside of the housing and the non-fluidics section is on the inside of the housing”

See Claim Construction Order, D.I. 89 (May 28, 2020).

43. I am informed that Judge Connelly adopted the following claim constructions.

Claim Term(s)	Court's Construction
“interchangeable modular component”	“component that can be inserted into and removed from positions in the housing and that has a standardized size and shape that allows it to be exchanged with another component”
“interchangeable modular fluid handling unit”	“fluid handling unit that can be inserted into and removed from positions in the housing and that has a standardized size and shape that allows it to be exchanged with another fluid handling unit”

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Claim Term(s)	Court's Construction
"modular fluid handling unit"	"fluid handling unit that has a standardized size and shape that allows it to be exchanged with another fluid handling unit"
Claim Preambles ("An automated liquid chromatography system comprising"/ "A method of modifying a fluid flow path in an automated liquid chromatography system comprising"/ "A method for building an automated liquid chromatography system, the method comprising"/ "A liquid chromatography system arranged to provide a controlled fluid flow through a chromatography column, the system comprising")	The preambles are claim limitations.
"liquid chromatography system"	Plain and ordinary meaning
"automated liquid chromatography system"	Plain and ordinary meaning
"wherein the system is capable of performing automated liquid chromatography"	Plain and ordinary meaning
"non-fluidics section"/"non-fluidics section"/"non fluidics section"	"a section of the interchangeable fluid handling unit that includes electrical components and does not include fluidics components"
"a fluid handling section"/"a fluidics section"	"a section of the interchangeable fluid handling unit that includes fluidics"

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Claim Term(s)	Court's Construction
	components and does not include non-fluidics components"

*Id.*

44. I have been informed that the Court rejected Bio-Rad's proposed constructions for the terms "non-fluidics section"/"non-fluidics section"/"non fluidics section" and "a fluid handling section"/"a fluidics section." Bio-Rad sought the following constructions for these terms:

"non-fluidics section"/"non-fluidics section"/"non fluidics section"	"a fluid handling section"/"a fluidics section"
"all the non-fluidics/electrical components of an interchangeable fluid handling unit"	"all the fluidics components of an interchangeable fluid handling unit"]

45. As can be seen, the Court did not accept Bio-Rad's construction of these terms. I have been provided with portions of the transcript of the hearing Judge Connolly held regarding claim construction. Judge Connolly made several statements regarding why he did not accept Bio-Rad's constructions. In one example, the Court stated

But, see, actually, this is very interesting that you propose this. If you recall, I actually led with the questions that exactly went to this issue, because my first

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question was about, can you have, do you have to have electronic components in the fluidics section, because I think it's clear that the written description allows for there to be non-fluidic components external to the non-fluidics section. They just, and I think this is a key, they just can't be in the fluidics section.

Markman Tr. 97:16-25. *See also*:

So I'm not able to accept GE's position that on one hand a non-fluidic section can contain fluidics. On the other hand, a fluidics section cannot contain non-fluidics. On the other hand, the patent uses the indefinite article, so it contemplates one or more sections, and the Federal Circuit has said, understandably, that the indefinite article does not mean all. So that is what I find problematic about Bio-Rad's construction, is they want to say all the fluidic components.

*Id.* at 100:14-23. Finally, *see also*:

That does not, however, preclude the possibility that there are other sections that are in the invention, and that's important because that is consistent with the use of the indefinite article, which is inconsistent with Bio-Rad's insistence that "all," either fluidic or non-fluidic components, are in the respective handling unit.

*Id.* 103:8-13.

46. Judge Connolly's statements are consistent with the Asserted Patents, which, as I discussed, teach multiple different modules where electronics are located in locations other than their respective non-fluidics sections. *See* Paragraphs 29-30.

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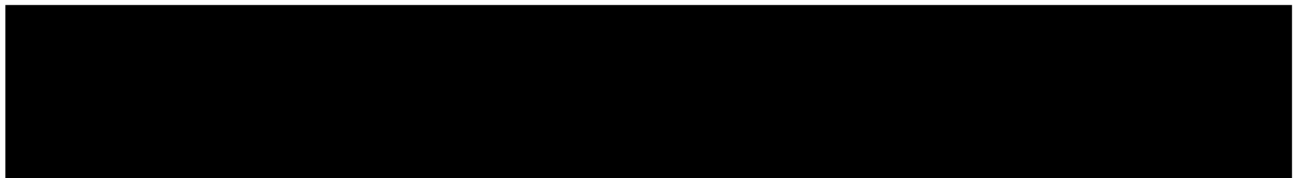
## **VII. BACKGROUND**

47. Chromatography is a method for separating chemical components. There are many different kinds of chromatography. Common to many types chromatography is that chemical components (called the mobile phase) are separated by flowing them over a stationary material (called the stationary phase) for which those chemical components have varying degrees of affinity, i.e. they are attracted to greater or lesser degrees to the stationary phase. These differing degrees of affinity allow some of the chemical components to move faster than others, separating the originally mixed chemical compounds into discrete bands. When performed with liquid chemical compounds, this process is called liquid chromatography. Modern day liquid chromatography is a very complicated process, used for either diagnostics—analyzing the chemical components of a fluid or production—separating some desired chemical component from a fluid for the purpose of collecting that component or components for subsequent use. Both applications of liquid chromatography are very complicated, requiring many different fluid operations to be performed precisely in succession in order for the chromatography to succeed. Automated fluid handling is a critical part of modern

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day automated liquid chromatography. These concepts are discussed in detail in my textbook, Ngyuen, Wereley and Shaegh, 2018.

48. Before Cytiva<sup>2</sup> invented the subject matter claimed in the Asserted Patents, automated liquid chromatography systems were complicated, as well as difficult to modify and use. Before introducing its ÄKTA avant system, Cytiva sold several different liquid chromatography systems, for example the ÄKTA Explorer. The inventors recognized the issues identified here, and sought to overcome them with the inventions disclosed and claimed in the Asserted Patents. For example, an early design document evidencing the work performed to develop the inventions noted that a goal was to eliminate what it referred to as a [REDACTED] of tubing users end up with when using prior art systems:



Ex. 1 (GEHCDEL127450 at 52).

49. In another example, before introducing its NGC system that is the subject of this litigation, Bio-Rad sold a liquid chromatography system called the

---

<sup>2</sup> For ease of discussion, I am using Cytiva to refer to both Cytiva and its predecessors.



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DuoFlo. Bio-Rad witnesses testified regarding the drawbacks of Bio-Rad's DuoFlo.

For example, Mr. Iovanni testified:

[REDACTED]

[REDACTED]

[REDACTED]

Iovanni Tr. 64:8-20. Mr. Chapman provided similar testimony:

[REDACTED]

[REDACTED]

[REDACTED]

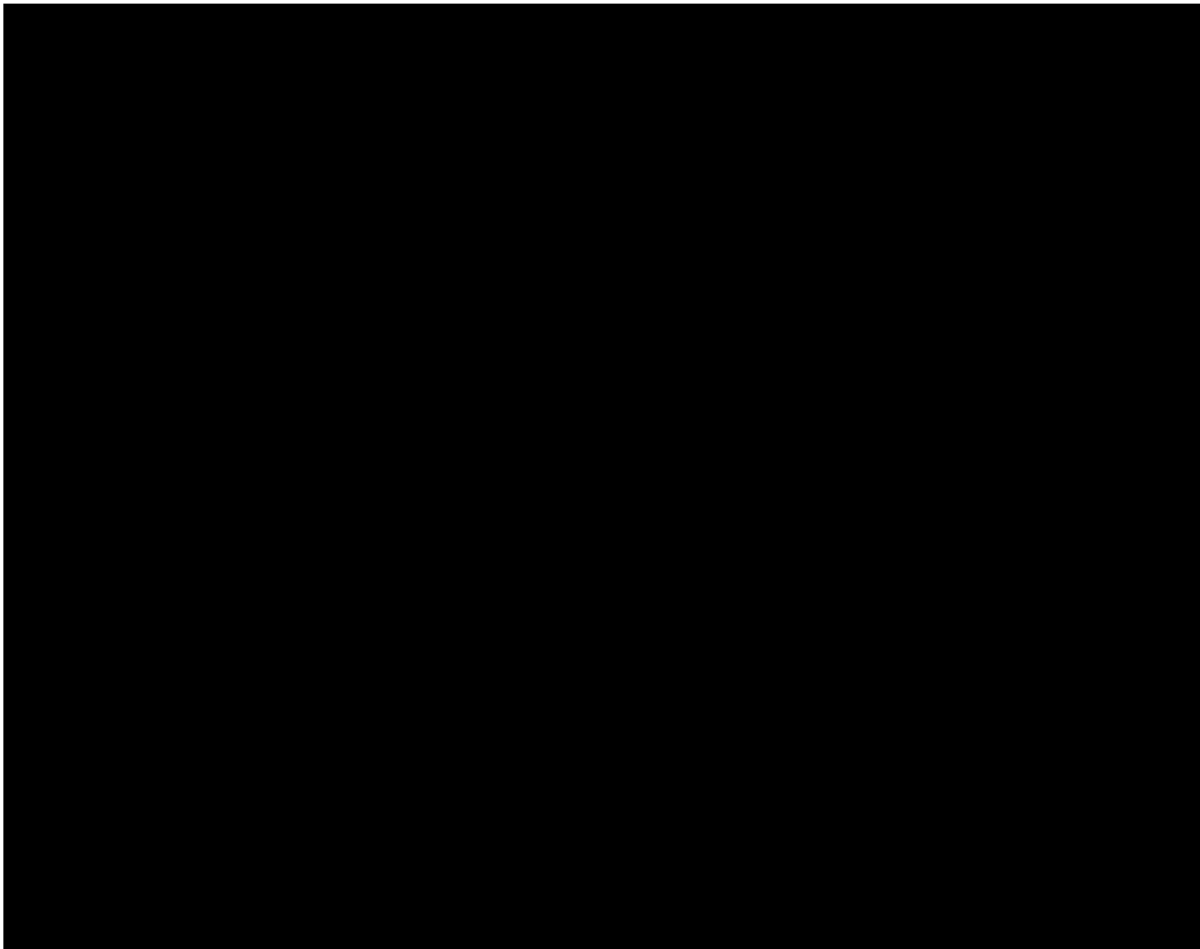
[REDACTED]

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Chapman Tr. 489:22-490:17.

50. Bio-Rad's own internal documentation provides additional evidence that even Bio-Rad recognized that prior products were, as Messrs. Iovanni and Chapman put it, [REDACTED]

[REDACTED]:” This presentation, dated in September 2009, is a good example:



Ex. 4 (BRGE00016967).

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51. The slide above shows, side-by-side,

When asked about this slide

at his deposition, Mr. Iovanni reiterated his testimony regarding the DuoFlo, and compared that design to what he referred to as a [REDACTED] of the NGC system BioRad was contemplating:

10 of 10

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

10 of 10

\_\_\_\_\_

\_\_\_\_\_

██████████

\_\_\_\_\_

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[illegible]

Iovanni Tr. 201:6-202.22.

## VIII. INFRINGEMENT

52. In the following paragraphs, I provide a detailed discussion of how the Accused Products meet the limitations of the patents-in-suit.

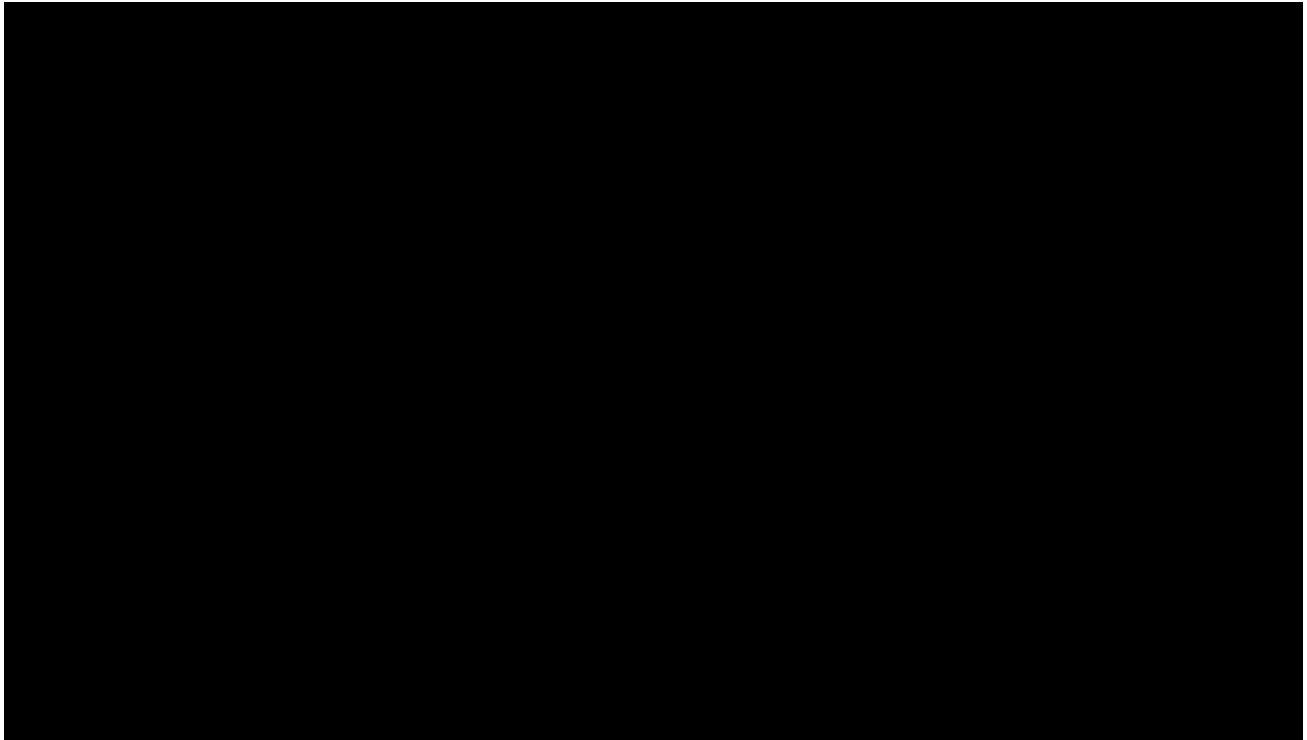
53. Before analyzing each of the asserted claims against Bio-Rad's NGC system, I will provide some background regarding the various models within the product line.

54. Bio-Rad's NGC system has four main models, with each module having sub-models. These four models are:

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- Quest
- Scout
- Discover
- Discover Pro

55. The following table, from an internal Bio-Rad document, demonstrates the differences between the models as well as the sub-models for each:



See BRGEDEL000070409.

56. As can be seen, the Quest model comprises, among other items, a base frame, two system pump modules, two blank modules, a sample inject valve module, a UV detector module, and a mixer module. The Quest 10 includes two F10 system

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pumps while the Quest 100 includes two F100 pumps, with the main difference between the two being the flow rate of each (0.001-10 ml/min for the F10 versus 0.010-100 ml/min for the F100). Ex. 5, p. 30. Both the Quest 10 and Quest 100 are available as the Quest 10+ and the Quest 100+. The difference between the “+” and the non-+” models is that the “+” modules come standard with multi-wavelength UV detectors.

57. As can also be seen, the Scout model comprises, among other items, a base frame, two system pump modules, two blank modules, a sample inject valve module, a UV detector module, a buffer blending valve module, a pH valve module, and a mixer module. The Scout 10 includes two F10 system pumps while the Scout 100 includes two F100 pumps. As discussed, the main difference between the F10 and F100 systems pumps is the flow rate of each (0.001-10 ml/min for the F10 versus 0.010-100 ml/min for the F100). Ex. 5, p. 30. Both the Scout 10 and Scout 100 are available as the Scout 10+ and the Scout 100+. The difference between the “+” and the non-+” models is that the “+” modules come standard with multi-wavelength UV detectors.

58. As can also be seen, the Discover model comprises, among other items, a base frame, an expansion frame (i.e., housing), two system pump modules, a

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sample pump module, two inlet valve modules, a sample inject valve module, a multi-wavelength UV detector module, a buffer blending valve module, a pH valve module, a column switch module, and a mixer module. As with the Quest and Scout, the Discover 10 includes two F10 system pumps while the Discover 100 includes two F100 pumps.

59. Finally, the Discover Pro model comprises, among other items, a base frame, two expansion frames (i.e., housings), two system pump modules, a sample pump module, three blank modules, three inlet valve modules, a sample inject valve module, a multi-wavelength UV detector module, a buffer blending valve module, a pH valve module, a column switch module, an outlet valve module, and a mixer module. As with the Quest and Scout, the Discover Pro 10 includes two F10 system pumps while the Discover Pro100 includes two F100 pumps.

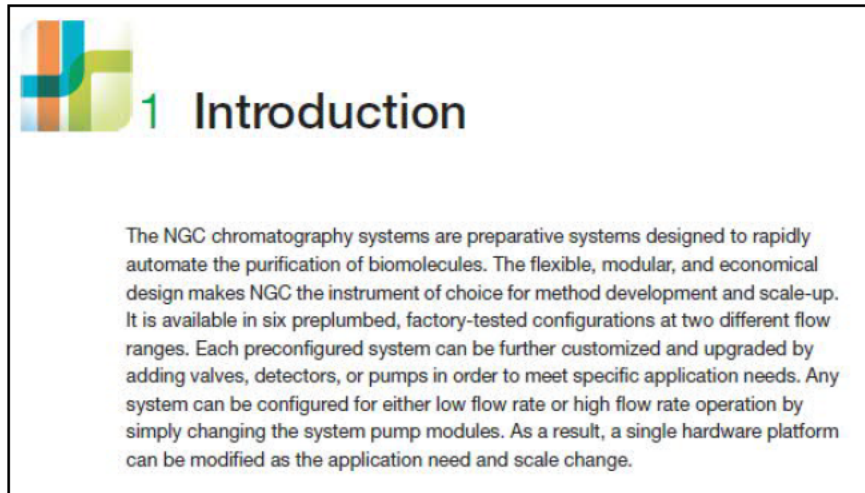
**A. The '420 Patent**

**1. Claim 1**

**a. “An automated liquid chromatography system”**

60. Bio-Rad's NGC system is an “automated liquid chromatography system.” First, there can really be no dispute that Bio-Rad's NGC is a “liquid chromatography system,” as its documents are replete with statements saying as such. One example is in the NGC Instrument Guide:

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Ex. 5, p. 11. Note that this document not only states that the NGC system is a liquid chromatography system, but it also notes that the NGC system “rapidly automates” purification of biomolecules. Thus, a POSITA would understand that the NGC system is an automated liquid chromatography system.

61. At her deposition, Dr. Mavandadi [REDACTED]

[REDACTED]

[REDACTED] See Ex. 6

(BRGE00065119). When asked about this at her deposition, Dr. Mavandadi testified that [REDACTED]

[REDACTED]

[REDACTED]



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[REDACTED]

[REDACTED]

[REDACTED]

Mavandadi Tr. 106:5-15.

62. This is plainly the case with the NGC system. [REDACTED]

[REDACTED]

[REDACTED]. Thus, the NGC system is plainly an “automated liquid chromatography system.”

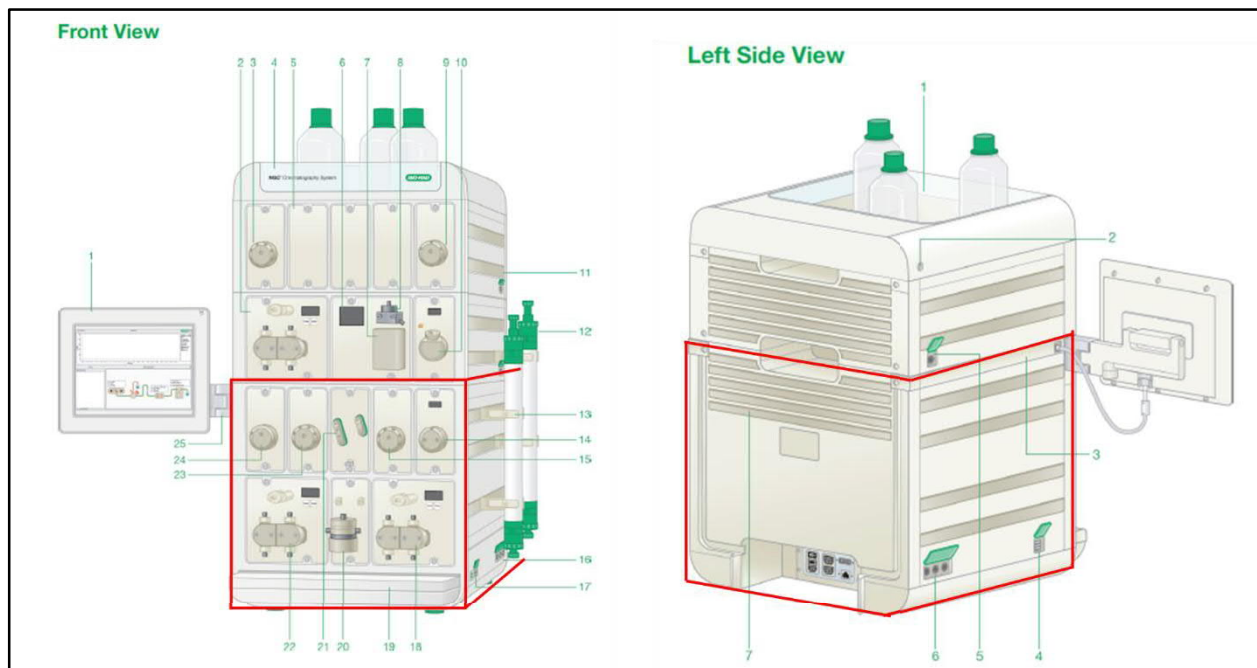
63. Moreover, automated liquid chromatography systems must have certain components to perform liquid chromatography, including at least an injection valve, a suitable pump, an inline detector that can measure the relevant characteristics of the liquid exiting the chromatography column, and control software for processing, displaying, and/or storing the results, which operate without manual intervention.

64. There is no dispute that Bio-Rad’s NGC system has each of these. I will discuss these in more detail below, but as will be seen, all Bio-Rad NGC models come standard with a sample inject valve module (Ex. 5, pp. 28, 87), two system pump modules (Ex. 5, pp. 28, 87), and a UV monitor module (Ex. 5, pp. 65-70, 87).

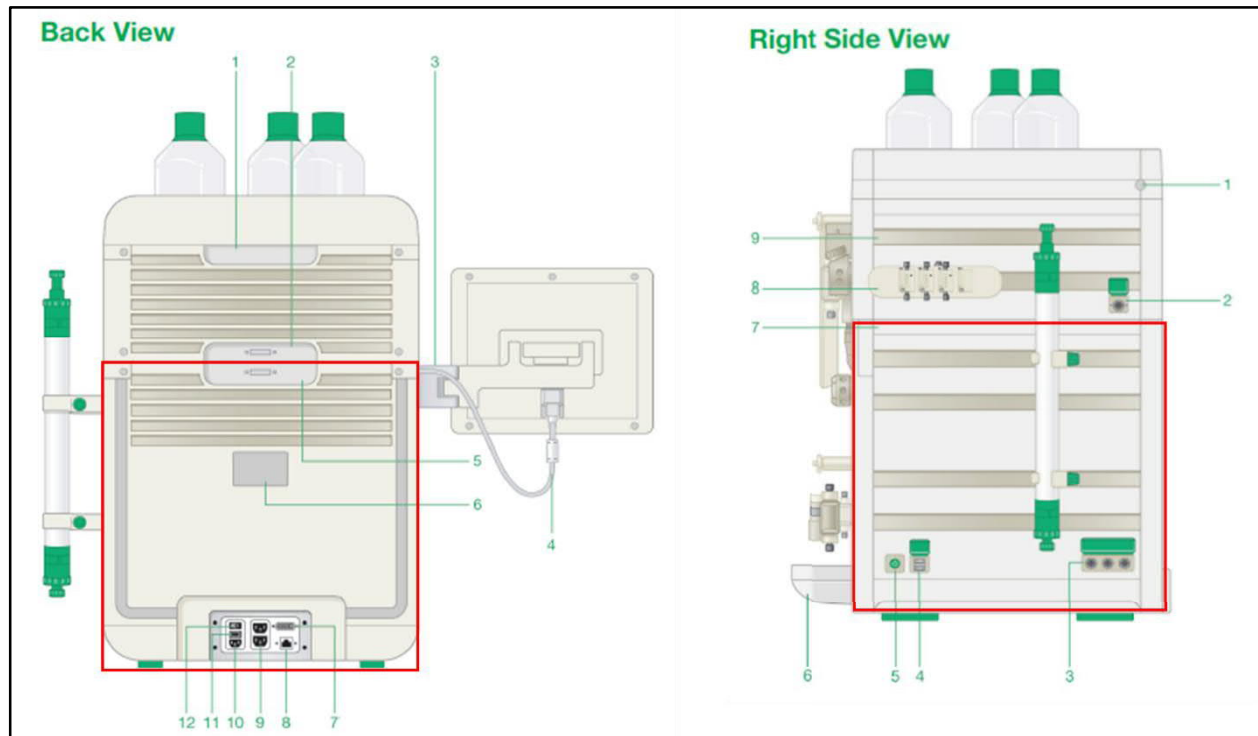
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**b. “a housing”**

65. The NGC system plainly has a housing unit. The following two figures, which are annotated to show the housing, come from Bio-Rad's NGC Instrument Guide:”



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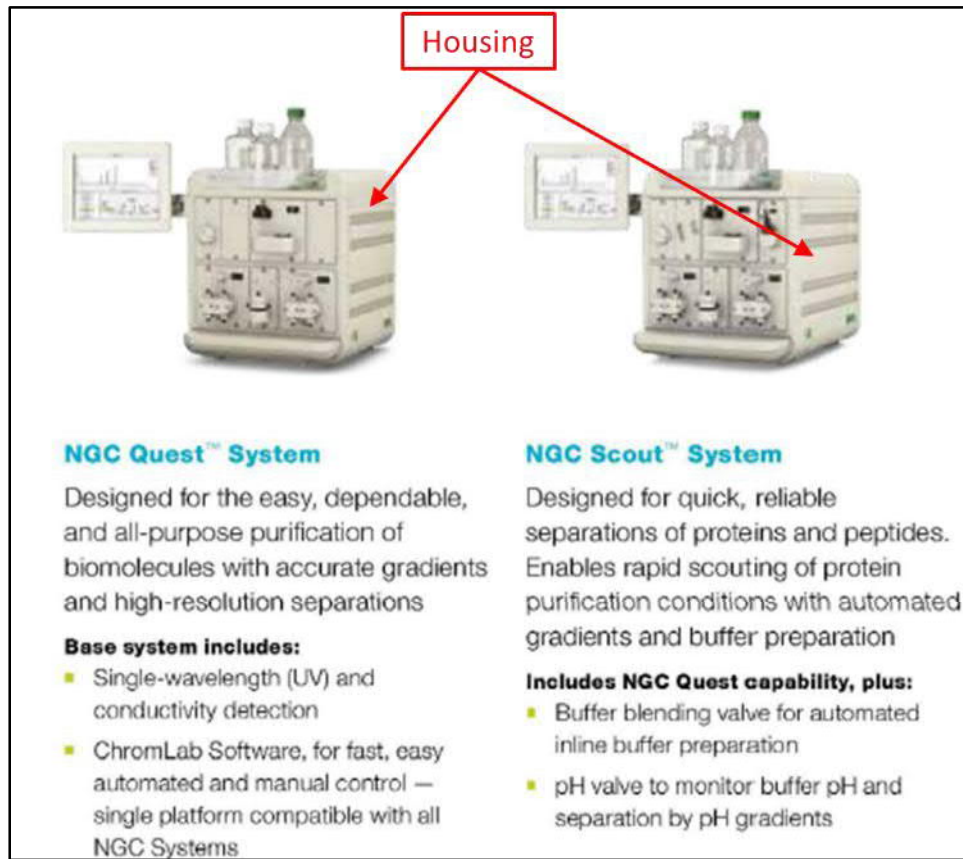


Ex. 5, p. 22, 24-26.

66. The “housing” is annotated in red. Note that the front view appears to depict a Discover Pro system, as it shows two expansion housings placed on top of the main enclosure. The remaining views appear to show a Discover system since they each show the NGC system with a single expansion housing stacked on the main housing.

67. Exhibit 21, a Bio-Rad marketing document, shows a good view of the Quest and Scout systems. A portion is reprinted them below, with an annotation pointing to the housing:

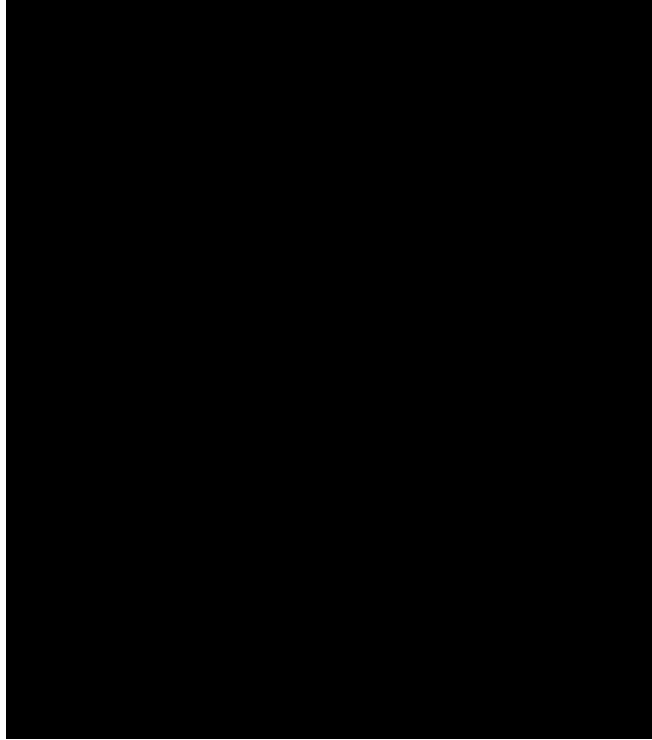
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Ex. 21, p. 3.

68. The “Assembly Procedure For Quest 10 Chrom 10 System NGC,”  
Bates No. BRGEDEL1541-1565 provides additional information:

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Ex. 24 BRGEDEL000001591.

69. Exhibit 12 is the Technical Specification for the Next Generation Chromatography System. [REDACTED]

[REDACTED]

[REDACTED] BRGEDEL401625.

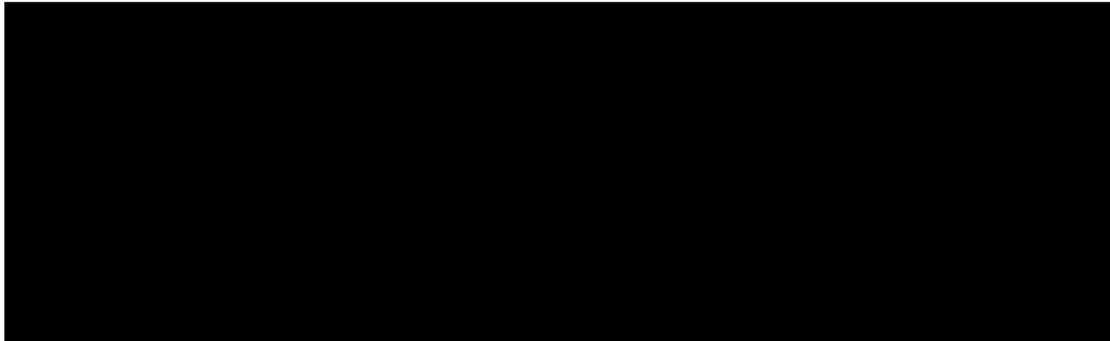
70. Mr. Iovanni testified that [REDACTED]

[REDACTED]. Iovanni Tr. 216:20-217:3. Exhibit 12 contains the following entry as a specification for the NGC:

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BRGEDEL401628. This document further demonstrates that the NGC system has a housing:



BRGEDEL401629. Mr. Bland testified that this entry refers to the housing of the NGC:



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[REDACTED]

Bland Tr. 86:2-86:17.

71. The hardware specification for the NGC's Primary system Enclosure (Ex. 11), further demonstrates that the NGC systems include a "housing:"

[REDACTED]

Ex. 11 (BRGEDEL445194). Mr. Chapman testified that this document reflects a housing as well:

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Chapman Tr. 541:6-541:22.

72. In sum, this claim element is plainly present in all NGC models.

**c. “a master control unit connected to a system bus;  
and”**

73. The NGC system has a master control unit connected to a system bus. The NGC system has several components that that fall within this claim term, either alone or in combination with each other. The “master control unit” reads on either the component that Bio-Rad often refers to as the “system controller” or “single board computer,” or the Chromlab computer, or the combination of the two.

74. I will focus first on Bio-Rad’s single board computer. Note that Mr. Iovanni testified that the terms master controller and system controller were used synonymously. Iovanni Tr. 170:22-171:8.



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75. Mr. Bland testified that the purpose of the single board computer in the NGC system was as follows:

[REDACTED]

Bland Tr. 36:1-36:13. Mr. Bland also testified that the single board computer was installed inside the housing: Bland Tr. 37:8-38:18.

76. Mr. Bland testified that the purpose of the external PC connected to the NGC system was follows:

[REDACTED]

Bland Tr. 36:14-37:2.

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77. The single board computer is also described in Exhibit 30.
78. Cytiva also took this photograph from the NGC it has:



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79. All of Bio-Rad's specifications for its various modules indicate that the CPUs (discussed below) on each of those modules communicate via [REDACTED]

[REDACTED]

Ex. 19 (BRGEDEL000282555) ([REDACTED])

[REDACTED]

Ex. 13 (BRGE0096083) ([REDACTED])

[REDACTED]

Ex. 14 (BRGEDEL000450748) ([REDACTED])

[REDACTED]

Ex. 20 (BRGEDEL000281533) ([REDACTED]).

[REDACTED]

Ex. 25 (BRGEDEL000451791) ([REDACTED])

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[REDACTED]

Ex. 26 (BRGEDEL000450859) [REDACTED]

[REDACTED]

Ex. 27 (BRGEDEL000450600) ([REDACTED]

[REDACTED])

80. Mr. Bland testified that single board computer communicates with each of the modules in the system via [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

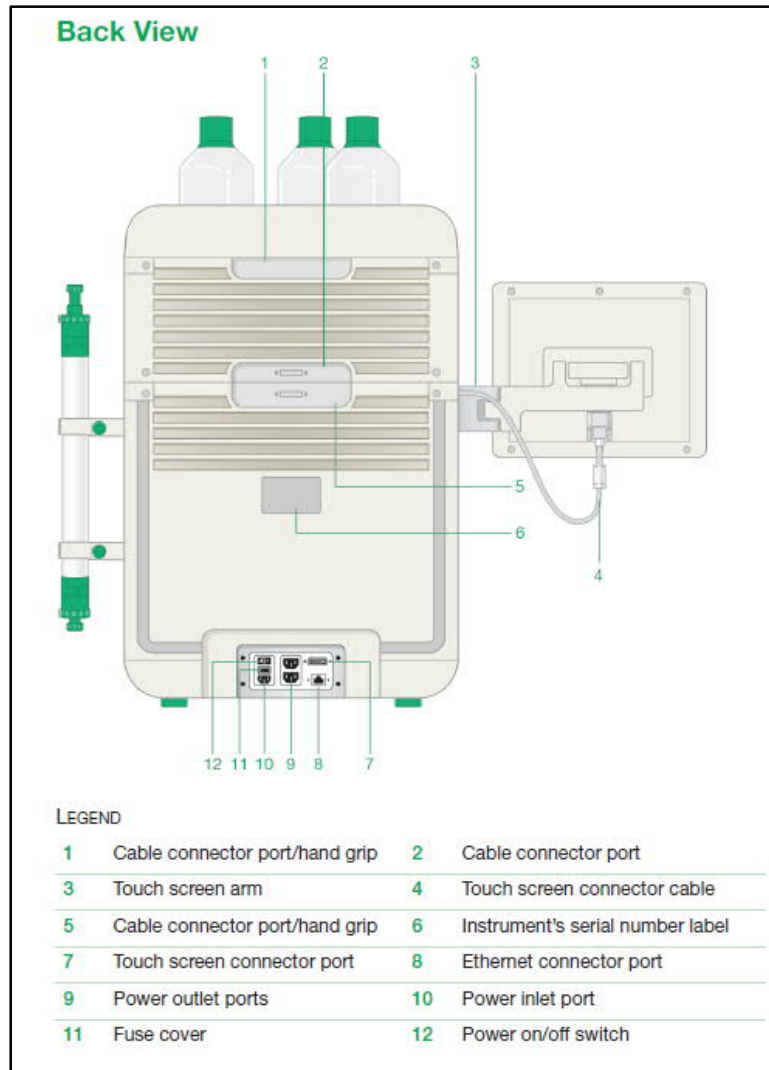
[REDACTED]

[REDACTED]

Bland Tr. 144:1-144:11.

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81. The external PC, which everyone will recognize contains a processing device (generally an Intel microprocessor, which will have several CPUs), also communicates via a system bus. See, e.g., Ex. 5:



Ex. 5, p. 24. See also:

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**Connecting the NGC System to the ChromLab Computer**

**Note:** Ensure that the ChromLab computer and the NGC instrument are powered off before beginning this task.

You can connect the NGC system to the ChromLab computer in one of two ways:

- Direct cable connection using a Cat 6 ethernet cable
- Network connection through your network infrastructure

Ex. 31 (Installation Guide), p. 79. Ethernet is a well-known bus.

82. In sum, this limitation is plainly present in all NGC models.

**d. “three or more fluid handling units arranged as interchangeable modular components comprising”**

83. All NGC models include “three or more” fluid handling units arranged as interchangeable modular components.”

84. As discussed, the Court construed “interchangeable modular component” to be a “*component that can be inserted into and removed from positions in the housing and that has a standardized size and shape that allows it to be exchanged with another component.*”

85. As discussed above, each NGC model can include the following modules:

	<b>Quest</b>	<b>Scout</b>	<b>Discover</b>	<b>Discover Pro</b>
1	System Pump	System Pump	System Pump	System Pump
2	System Pump	System Pump	System Pump	System Pump

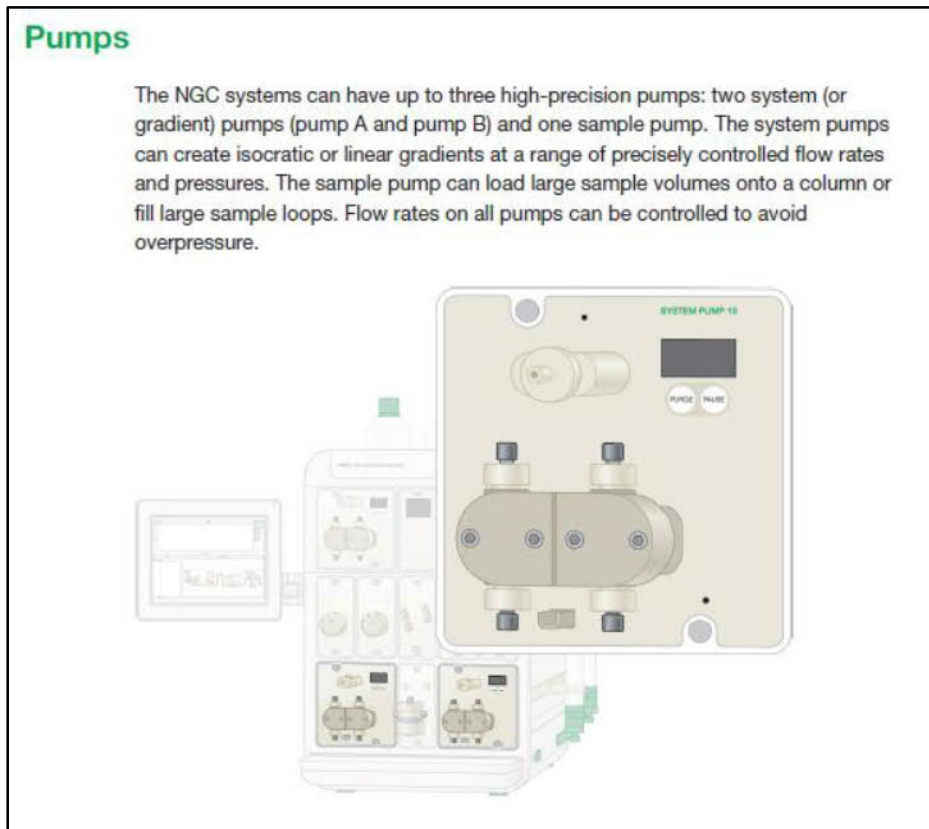
HIGHLY CONFIDENTIAL (TECHNICAL) - ATTORNEYS' EYES ONLY

	<b>Quest</b>	<b>Scout</b>	<b>Discover</b>	<b>Discover Pro</b>
3	Sample Inject Valve	Sample Inject Valve	Sample Inject Valve	Sample Inject Valve
4	UV Detector	UV Detector	UV Detector	UV Detector
5		pH Valve	pH Valve	pH Valve
6			Column Switch Valve	Column Switch Valve
7			Sample Pump	Sample Pump
8			Buffer Inlet Valve	Buffer Inlet Valve
9				Sample Inlet Valve
10				Outlet Valve

86. Per the language of this claim, only three of Bio-Rad's modules need be "interchangeable modular components." In each of the NGC models, each of the system pumps are an "interchangeable modular component," and are thus two of the three that the claim requires. A third "interchangeable modular component" is Bio-Rad's sample inject valve module, which is also standard on all NGC models.

87. Bio-Rad's Instrument Guide illustrates system pump modules:

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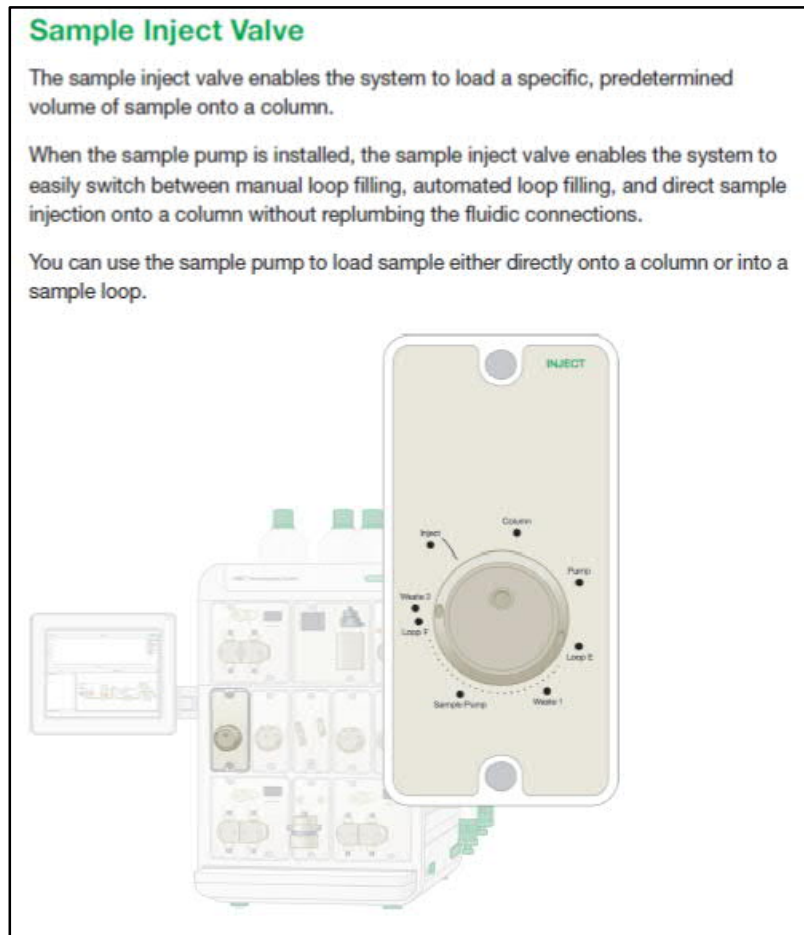


Ex. 5, p. 28.

88. Bio-Rad's Instrument Guide illustrates the sample inject valve module:



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Ex. 5, p. 37.

89. First, these modules, like all the NGC modules, can be inserted into and removed from positions in the housing.

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## 2 The NGC Instrument

The NGC instrument ships preassembled with the components necessary to perform gradient separations. The modular components slide into slots in the system known as *bays*. Some modules fit into single-wide bays while others require double-wide bays. Bays can be converted from one size to the other by adding or removing a center divider.

Each module has a unique electronic ID that enables the system to recognize its function when the module is placed into a bay. For example, the system can distinguish between a sample inject valve module and a sample inlet valve module even though they each occupy a single-wide slot.

The position of the module on the system can be changed to optimize the placement and minimize the length of tubing, reducing the system swept volume. The physical location of a module can be easily identified in the overall flow scheme required to run the application through the ChromLab software. Prior to starting a run, ChromLab performs a system check to ensure that all the required modules are physically present on the instrument.

This chapter explains in detail the modules that make up the NGC instrument.

*Id.*, p. 19. The Technical Specification for NGC indicates that [REDACTED]

[REDACTED]:

[REDACTED]

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Ex. 12 (BRGEDEL401642). This plainly indicates that all modules, including pump modules, sample inject valve modules, UV detector modules, and pH valve modules, “can be inserted into and removed from positions in the housing” and “exchanged with another component,” just as the Court’s construction requires. Mr. Bland testified as follows regarding this requirement:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

HIGHLY CONFIDENTIAL (TECHNICAL) - ATTORNEYS' EYES ONLY

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

Bland Tr. 98:13-101:1.

90. This same document indicates that [REDACTED] was required for each module:

[REDACTED]

Ex. 12 (BRGEDEL401629).

91. Each of the modules have a standardized shape and size. In particular, the NGC has system “bays,” or positions, that can receive the modules. This is seen in the excerpt from NGC Instrument Guide (Ex. 5) I pasted above (p. 19). This same document illustrates this in more detail. In a section of the Instrument Guide entitled “Replacing or Repositioning Modules on the NGC Instruments,” Bio-Rad shows the following:

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Ex. 5, p. 234. The NGC can accommodate modules that are “single-wide” and “double-wide.” This is shown below:

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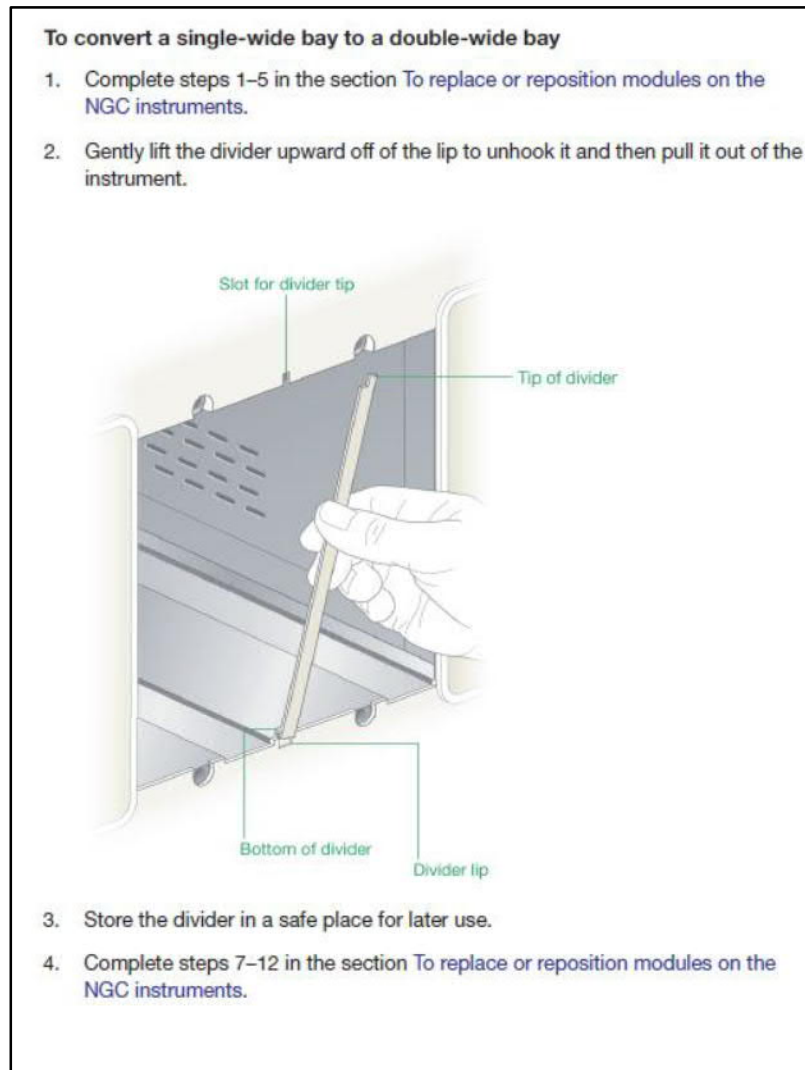
**Converting Bays to Fit Modules**

Some modules fit into single-wide bays while others require double-wide bays (such as the system and sample pump modules and the UV and UV/Vis detector modules). Bays can be converted from one size to the other by adding or removing the center divider.

The following image shows two adjacent, empty, single-wide bays.



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Ex. 5, pp. 236-238 (p. 236 not reproduced).

92. The pump modules are double-wide modules while the sample inject valve is a single-wide module. This plainly demonstrates that these modules have a “standardized size and shape.” For example, just as Bio-Rad instructs in the Instrument Guide, an NGC user could, for example, remove a sample inject valve



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module and insert into the single-wide bay another module, e.g., a pH valve module. Likewise, an NGC user could remove a pump module and insert into the double-wide bay, e.g., a sample pump or a UV detector. Similarly, an NGC user could convert the double-wide bay into a single-wide bay and insert a sample inject valve module into one of the two resulting single-wide bays.

93. Finally, by having these standard sized bays, the NGC system “allows [for the fluid handling unit] to be exchanged with another component.” Bio-Rad’s Instrument Guide makes that clear, as it indicates that a person can replace or reposition modules:

**Replacing or Repositioning Modules on the NGC Instruments**

**WARNING!** Disconnect power to the NGC instrument before removing or repositioning any module. Do not attempt to service any component on the NGC instrument unless noted in this manual. Contact Bio-Rad for service requests.

**WARNING!** To reduce the chance of liquid seeping into the instrument, all open bays must be filled with the NGC Blank module (catalog #788-4005). The NGC instrument will not operate if it detects a slot without a module inserted.

**To replace or reposition modules on the NGC instruments**

1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. If necessary, disconnect all tubing lines to and from the module that you plan to replace or reposition.
3. Loosen the captive screws on the front of the installed module.
4. Firmly grasp both screws on the module and pull it forward out of its bay.

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*See* Ex. 5, p. 233. *See also Id.* at 234-239.

94. Thus, this claim element is plainly met by all NGC models.

**e. “(i) an external fluidics section,”**

95. The “three or more fluid handling units arranged as interchangeable modular components” I identified above each have an “external fluidics section.”

96. As discussed, the Court construed “fluidics section to mean *“a section of the interchangeable fluid handling unit that includes fluidics components and does not include non-fluidics components.”*

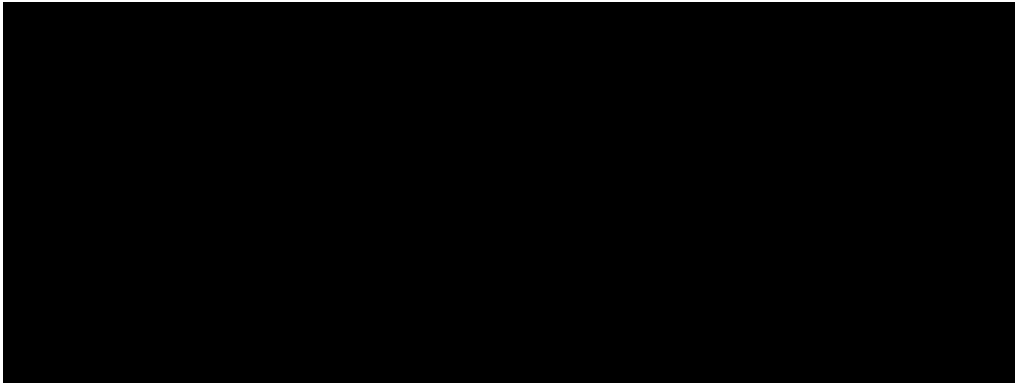
97. First, the specifications for each of these modules (and others) specify that they have a “fluidics section” because they state that [REDACTED]

[REDACTED]

[REDACTED]

Ex. 13 (BRGE0096090) [REDACTED]

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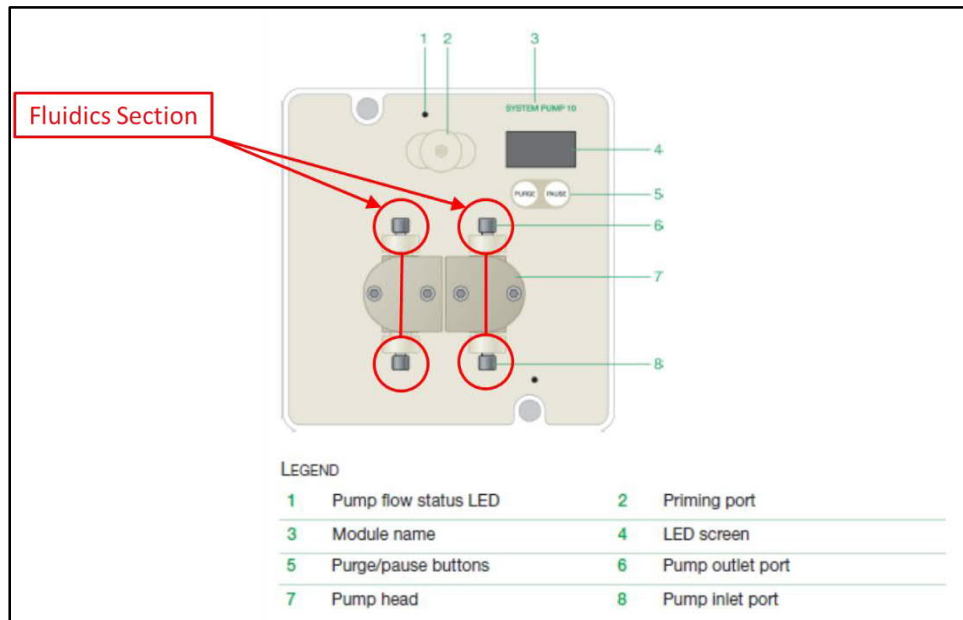
Ex. 14 (BRGEDEL000450753) ([REDACTED]).

98. Mr. Chapman testified that these specifications were met for the pump modules (Chapman Tr. 529:12-530:17) and sample inject valve module (Chapman Tr. 528:16-529:10).

99. These documents and Mr. Chapman's testimony demonstrates that the "fluidics section" for each of these modules, *e.g.*, the two system pump modules and the sample inject valve module "*include[] fluidics components,*" just as the Court's claim construction requires.

100. The fluidics section for the system pump modules used in the NGC system is as follows:

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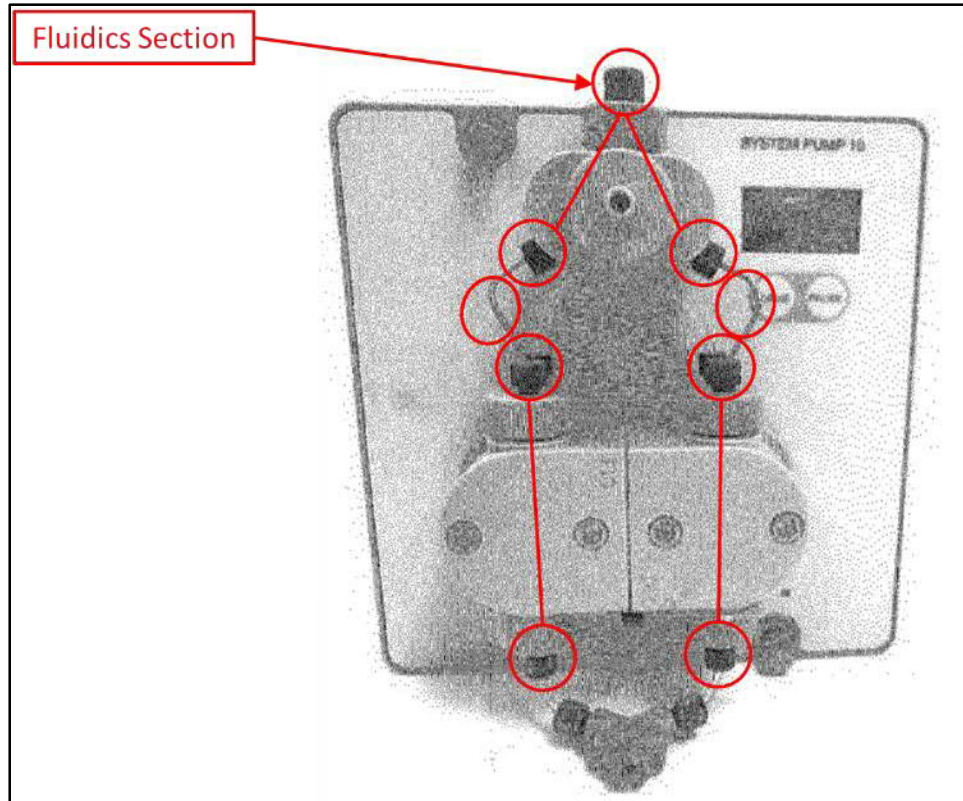
Ex. 5, pp. 28-29. Note that this figure annotated to show hidden portions of the fluidics section, *i.e.*, a simplified illustration of the flow path within the fluidics section.

101. Note that the NGC Instrument Guide illustrates the F10 pump module, but the F100 pump module is essentially identical for purposes of this infringement analysis, meaning that the structure corresponding to the recited fluidics section is the same.

102. Note also that this portion of the Instrument Guide does not illustrate the priming ports that can be on the system pump modules. These can be seen in the

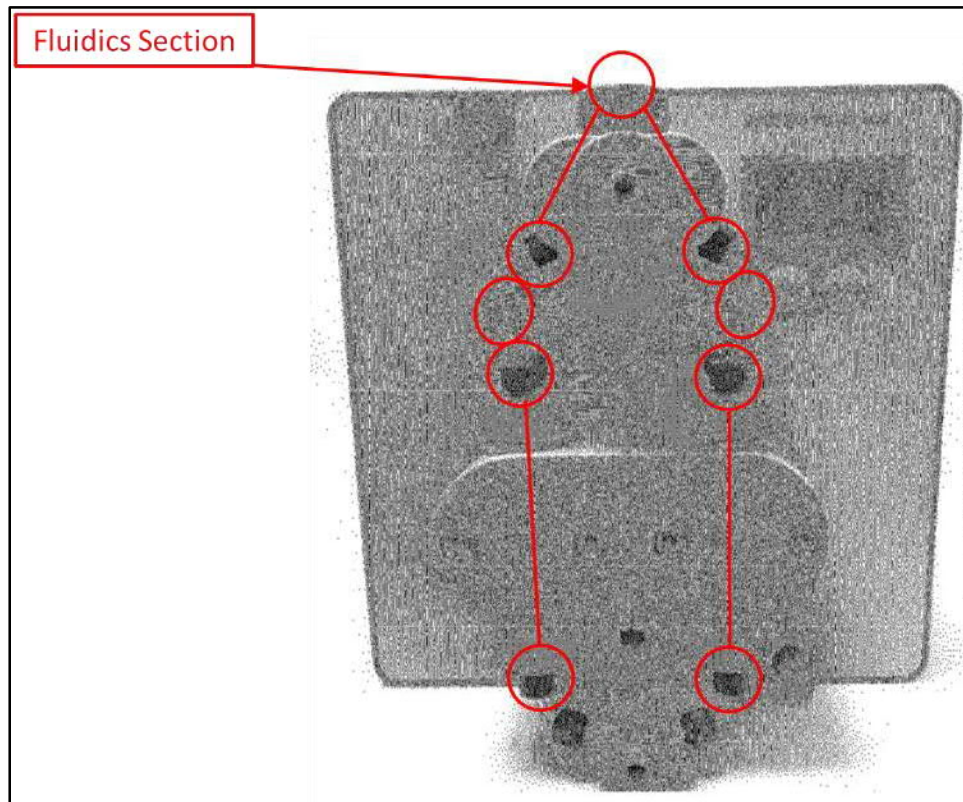
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assembly drawings, which is annotated to show the fluidics section, to show a simplified illustration of flow path within the fluidics section:



Ex. 23 (BRGEDEL1507) (F10 pump module). *See also:*

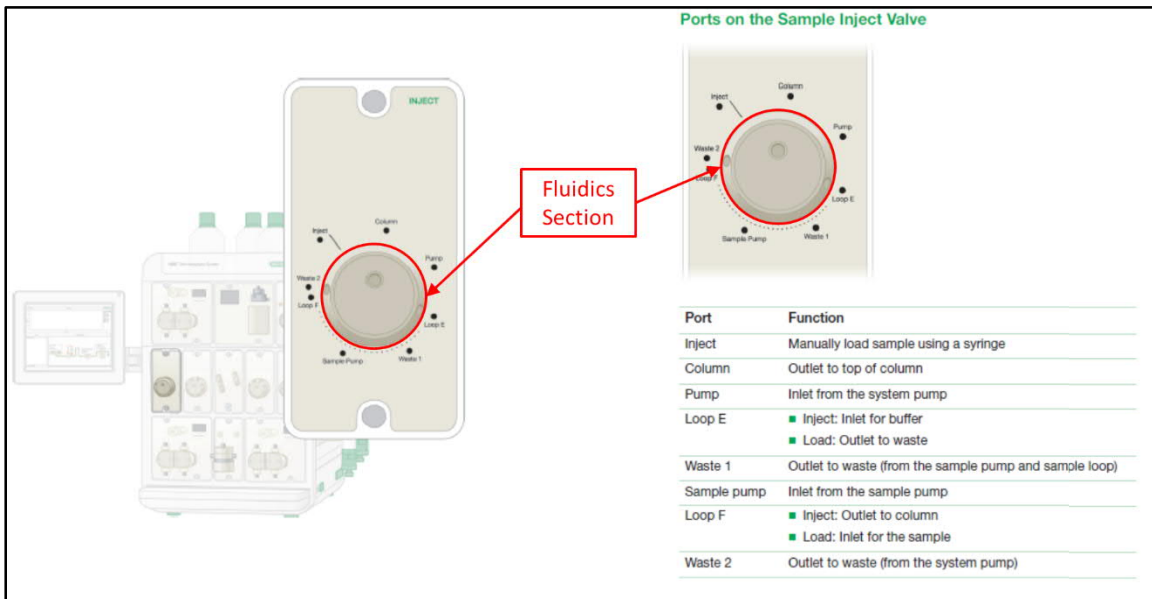
HIGHLY CONFIDENTIAL (TECHNICAL) - ATTORNEYS' EYES ONLY



Ex. 28, (BRGEDEL972) (F100 pump module)

103. The fluidics section for the sample inject valve module used in the NGC system is as follows:

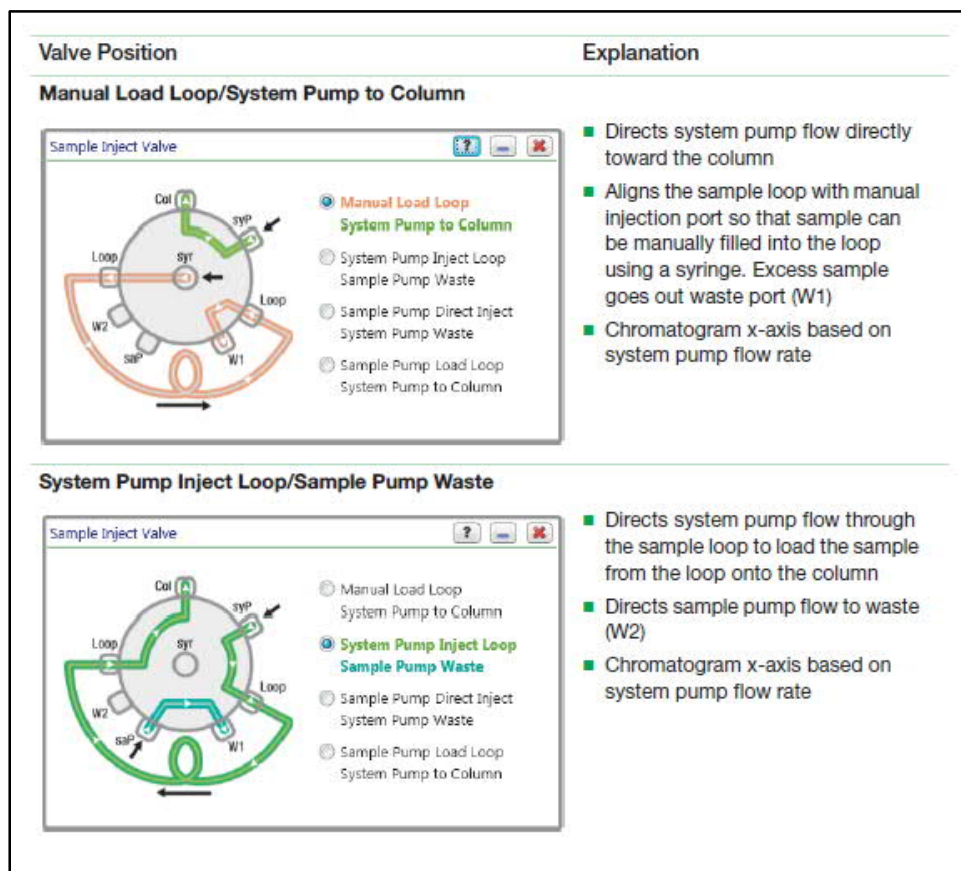
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Ex. 5, pp 37-38. This particular illustration does not show the complete fluid flow path, as the fluid flow paths of the fluidics section are not shown. However, this can be seen in, for example, the following figure from Bio-Rad's Instrument Guide:



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Ex. 5, p. 40.

104. As is seen, the fluidics section of each of these modules include fluidic components in the flow path like tubing inputs and outputs, sensors, flow cells and valve components.

105. The Court's construction also requires that the fluidics section "*not include non-fluidics components.*" None of the fluidics portions I have identified above contain non-fluidics components. They all are involved in transmission of fluids, e.g., tubing, flow cells, tubing inputs and outputs, etc.



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106. A POSITA would recognize that externally located non-fluidics components in Bio-Rad's NGC system are not a part of the claimed fluidics section. Indeed, as discussed, the Court stated at the claim construction hearing that there can non-fluidics components like electronics external to the housing. Markman Tr. 97:16-25. Indeed, the Court also said each module can have more than just a fluidics section and a non-fluidics section. *See e.g., Id.* at 100:14-23 and 103:8-13.

107. In sum, each model of Bio-Rad's NGC system has an external fluidics section, just as claimed.

**f. “(ii) an internal non-fluidics section”**

108. The “three or more fluid handling units arranged as interchangeable modular components” I identified above each have an “internal non-fluidics section.”

109. As discussed, the Court construed “non-fluidics section” to mean “*a section of the interchangeable fluid handling unit that includes electrical components and does not include fluidics components.*”

110. As discussed, the specifications for each of these modules (and others) specify that they have a “non-fluidics section” because they state that [REDACTED]

[REDACTED]

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[REDACTED] The specifications further state that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Ex. 13 (BRGE0096090) ([REDACTED])

[REDACTED]

Ex. 14 (BRGEDEL000450753) ([REDACTED])

111. Mr. Chapman testified that these specifications were met for the pump modules (Chapman Tr. 529:12-530:17) and sample inject valve module (Chapman Tr. 528:16-529:10).

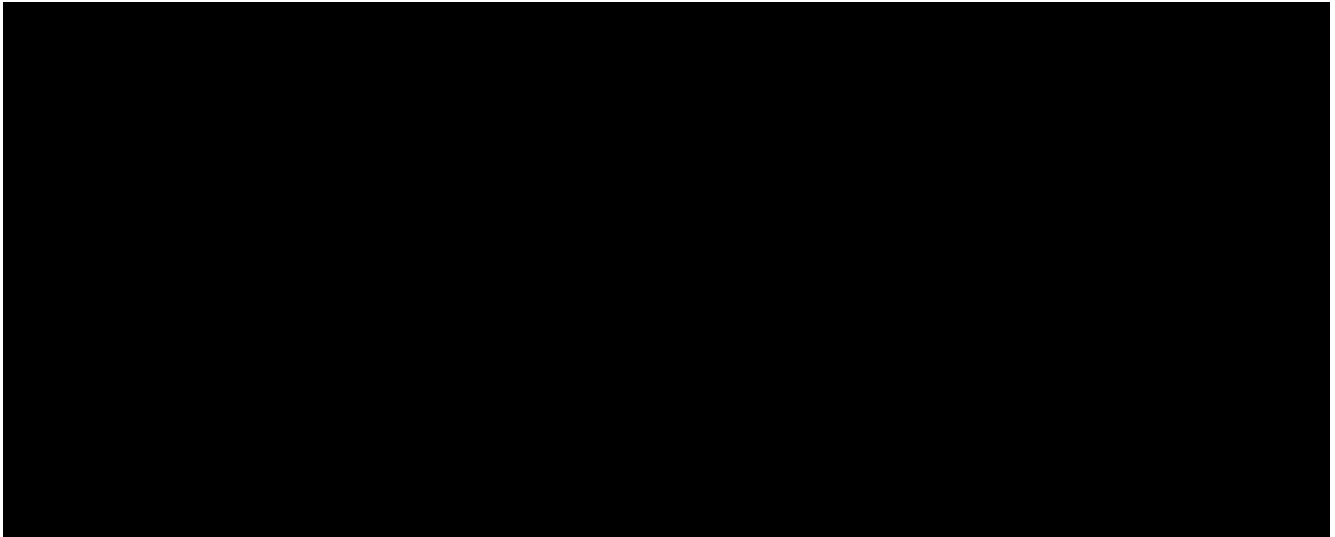
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112. The assembly drawings for these modules demonstrate that these modules have a non-fluidics section that include electronic components but not fluidics components

- F10 System pump module: Ex. 23.
- F100 System pump module: Ex. 28.
- Sample inject valve module: Ex. 29.

113. The NGC Service Manual (Ex. 16) further demonstrates that there is a non-fluidics section that is internal to the housing.

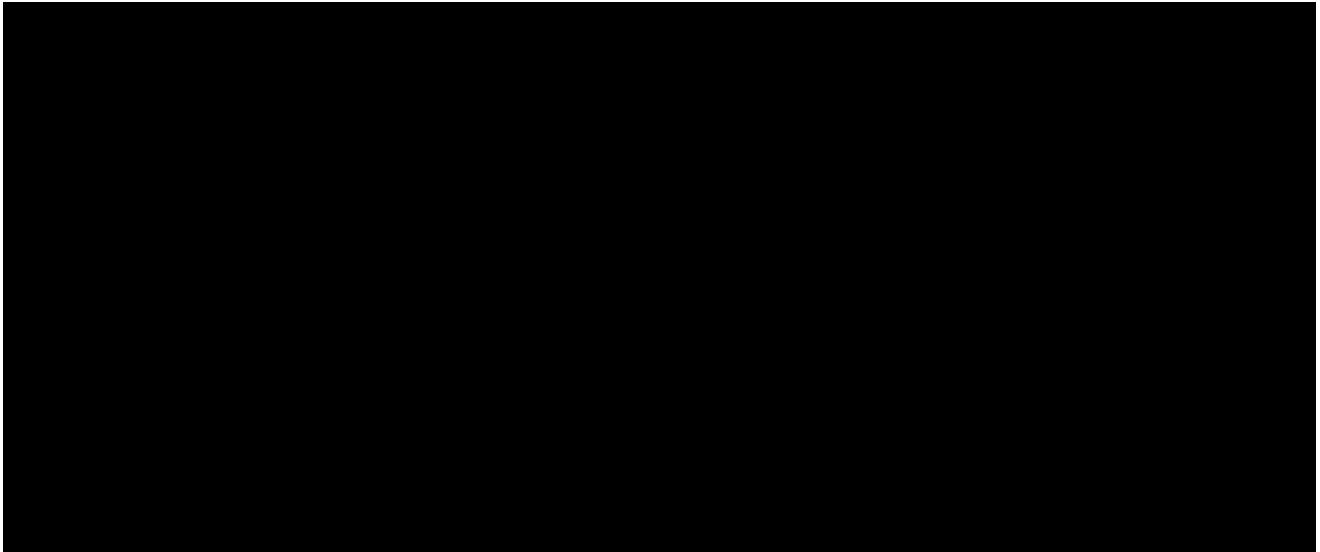
114. System pump modules:



Ex. 16 (BRGEDEL317444, BRGEDEL317555).

115. Sample inject module:

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Ex. 16 (BRGEDEL317453-317454, BRGEDEL317564).

116. These documents and Mr. Chapman's testimony demonstrates that the "non-fluidics section" for each of these modules, *e.g.*, the two system pump modules and the sample inject valve module "*include[] electrical components and does not include fluidics components,*" just as the Court's claim construction requires.

- g. "including a bus connector for directly connecting the interchangeable modular component with the system bus, and"**

117. The "three or more fluid handling units arranged as interchangeable modular components" I identified above each have a "bus connector for directly connecting the interchangeable modular component with the system bus."

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118. As discussed above, the NGC system has an [REDACTED] system bus. Mr. Bland testified that that the [REDACTED]  
[REDACTED] Bland Tr. 110:13-15.

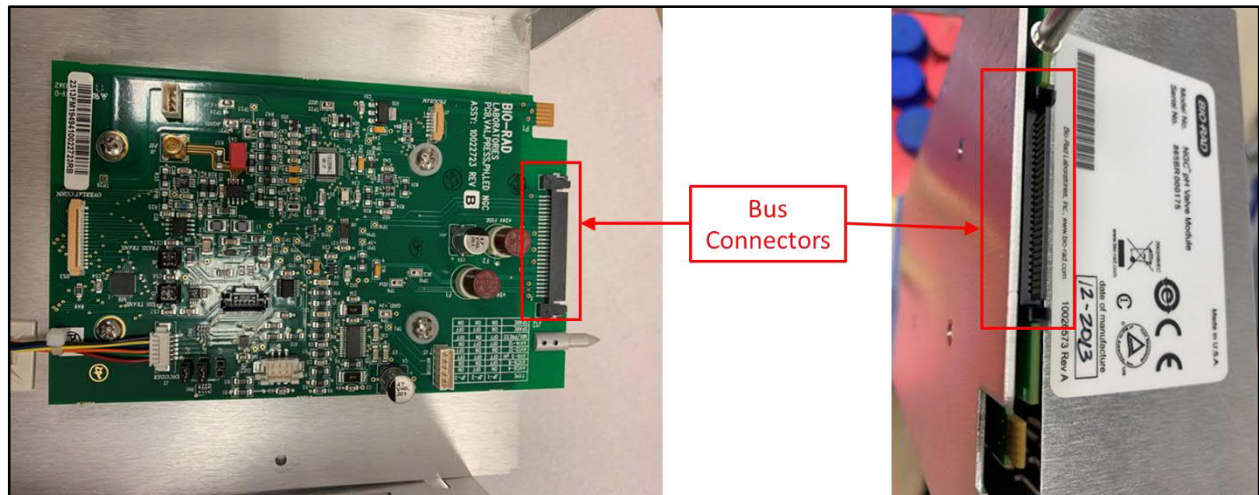
119. The two system pump modules and the sample inject valve module have bus connectors that directly connect them to [REDACTED]. Instrument Guide (Ex. 5) contains an illustration of an empty bay:



Ex. 5, p. 234. Note that this figure from Bio-Rad's Instrument Guide is a simplification, as it does not show the connector. However, as I will show below, connectors are plainly present.

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120. Each module has a bus connector that mates with a complementary connector on the backplane. Below are photographs Cytiva took showing the connector on a valve module that is annotated to show the connector:

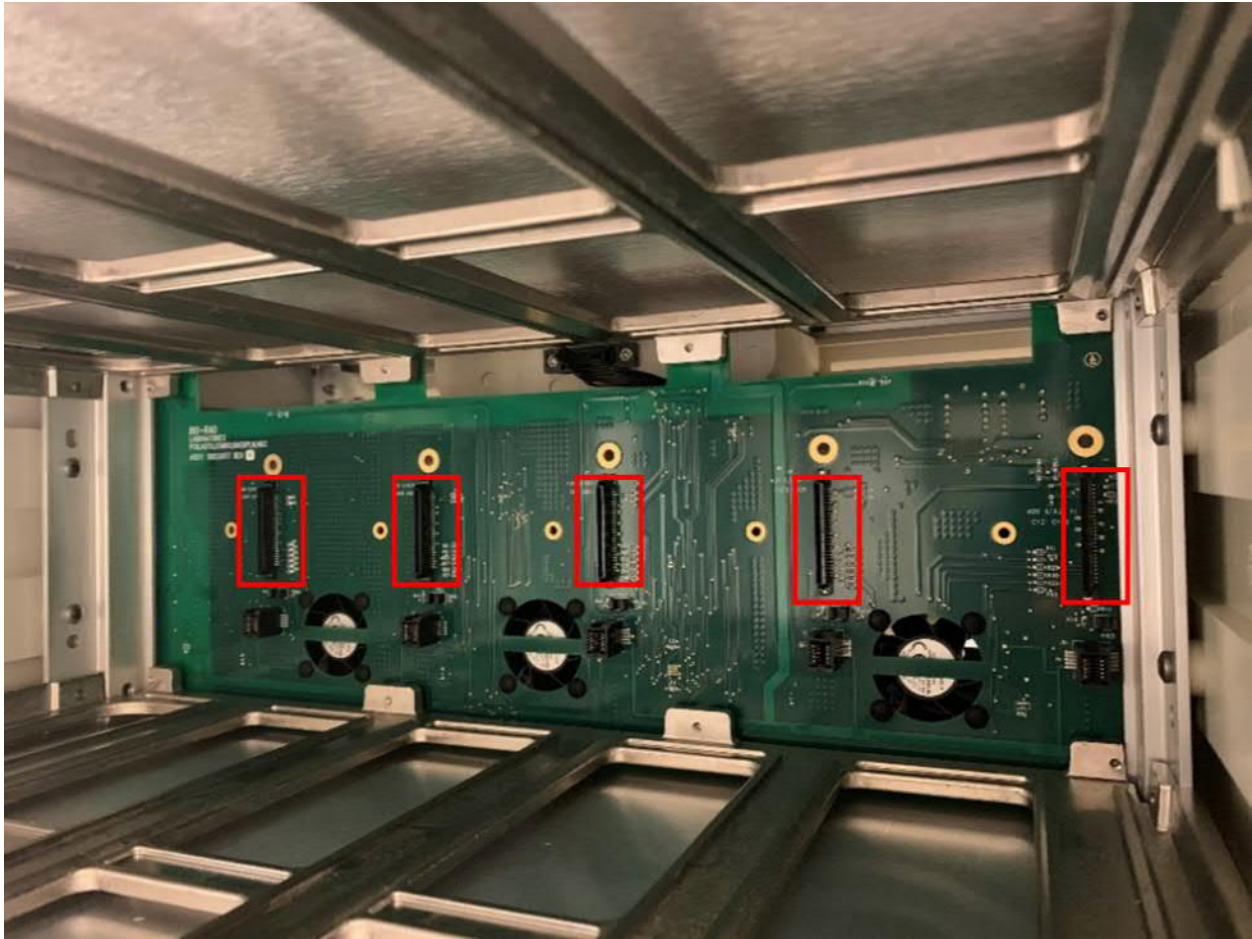


Certain of the pins on each connector will connect to the NGC system bus.

121. I was able to perform a video inspection of the NGC system that Cytiva has and confirmed that connectors like those in the above photographs are present on each module.

122. In addition, these bus connectors “directly connect[]” each of the modules “with the system bus.” As seen below in another photograph taken by Cytiva, the backplane in the NGC system has connectors that receive and mate with the bus connectors on each module:

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123. Bio-Rad's NGC Instrument Guide states the following:

9. Place the module into the open bay and gently push it in as far as it will go.

**Note:** Each module has an alignment pin on the back to ensure that it aligns correctly with the main communication board.

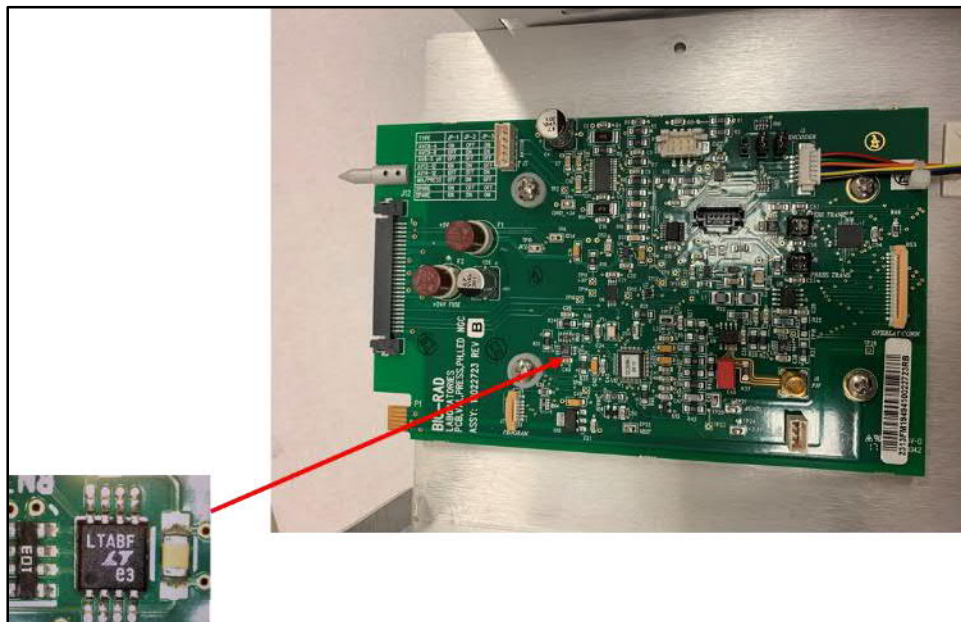
Ex. 5, p. 235.

124. The alignment pin on each module ensures that the connector on the module and the connector on the NGC backplane mate properly.



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125. As discussed above, the system bus is [REDACTED]. Each module contains a bus controller. I confirmed this with Cytiva, who took the following photographs of an NGC module they have, and they were able to determine that the module has a Linear Technology LTC4300A Hot Swappable 2-wire bus buffer, further establishing that there is a bus:



126. The connection between [REDACTED] on the module and [REDACTED] on the backplane is direct because the electrical signals pass directly between the module and the backplane.

127. Thus, this claim element is present in each of Bio-Rad's NGC models.

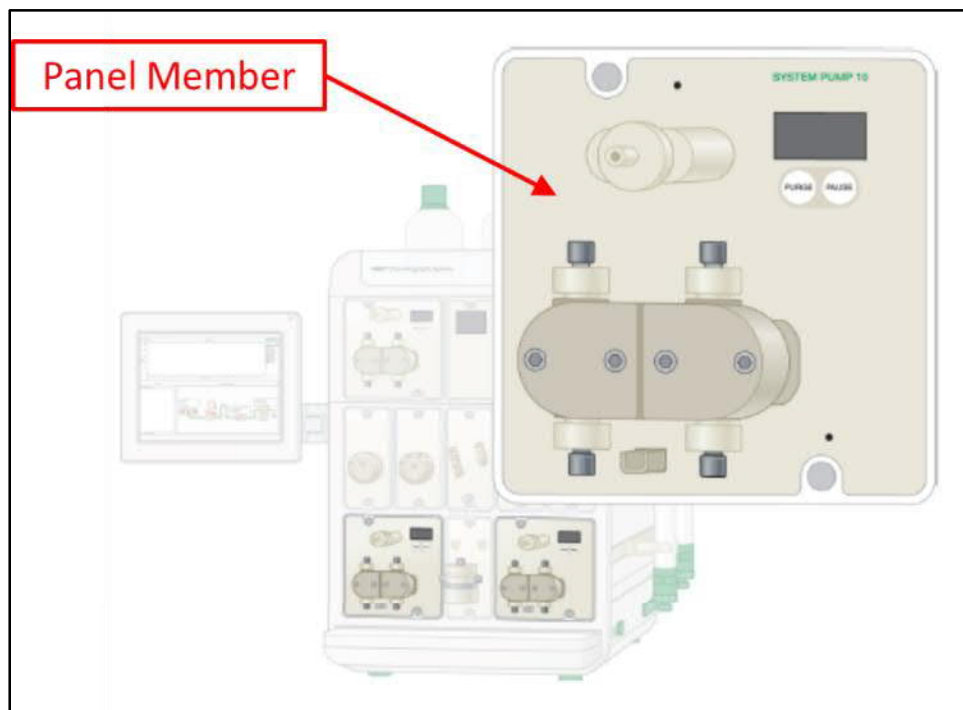


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**h. “(iii) a panel member arranged to separate the fluidics section from the non-fluidics section;”**

128. The “three or more fluid handling units arranged as interchangeable modular components” I identified above each have a “panel member arranged to separate the fluidics section from the non-fluidics section.” As discussed, a panel member is a third section that makes up a module. The structures that correspond to the claimed “panel member” for each of these modules is as follows:

129. The panel member for the two system pump modules is identified below:

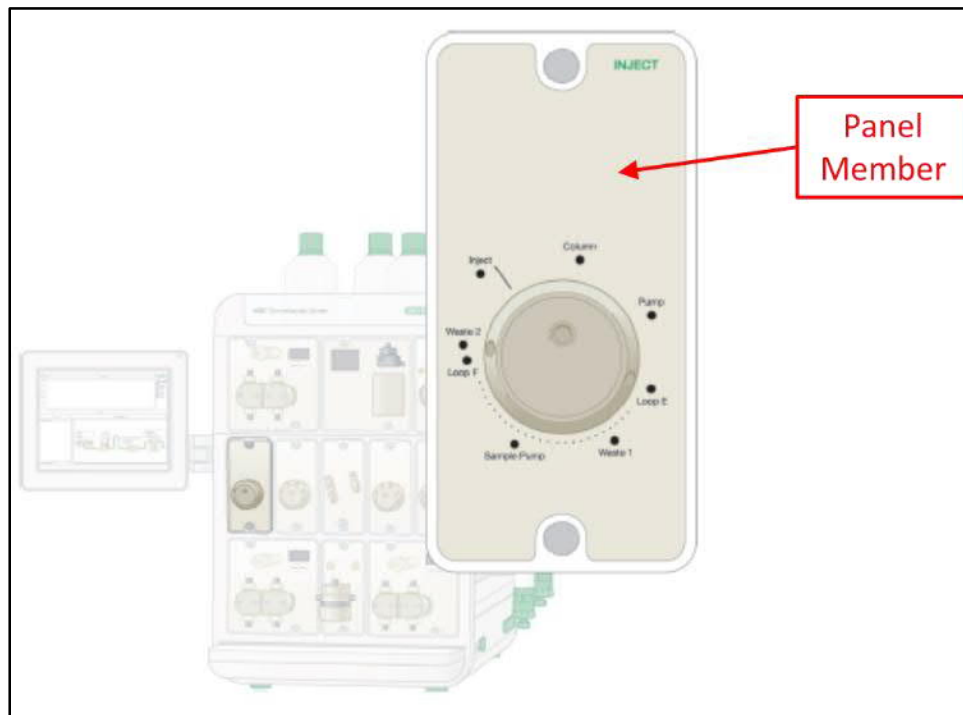


Ex. 5, p. 28.

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130. Note that the panel member for the F100 pump module is, for purposes of the infringement analysis, is the same as for the F10 pump module shown above.

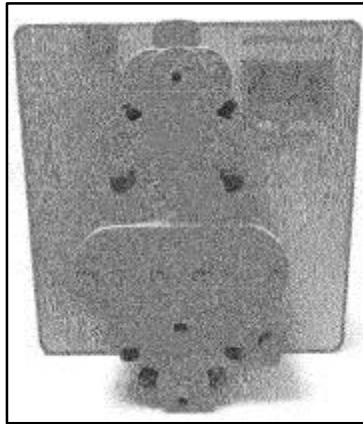
131. The panel member for the sample inject valve module is identified below:



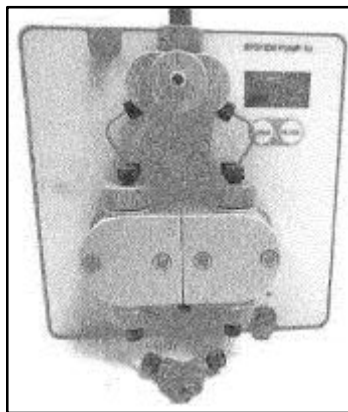
Ex. 5, p. 37.

132. Further evidence that these modules have a panel member is seen in Bio-Rad's assembly drawings:

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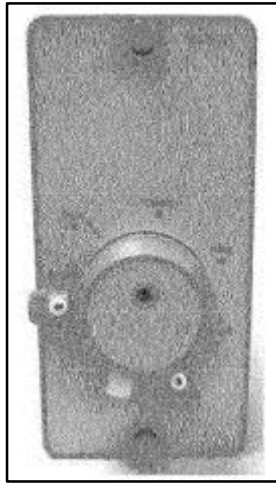


Ex. 28 (BRGEDEL000000972) (100 mL Pump Module)



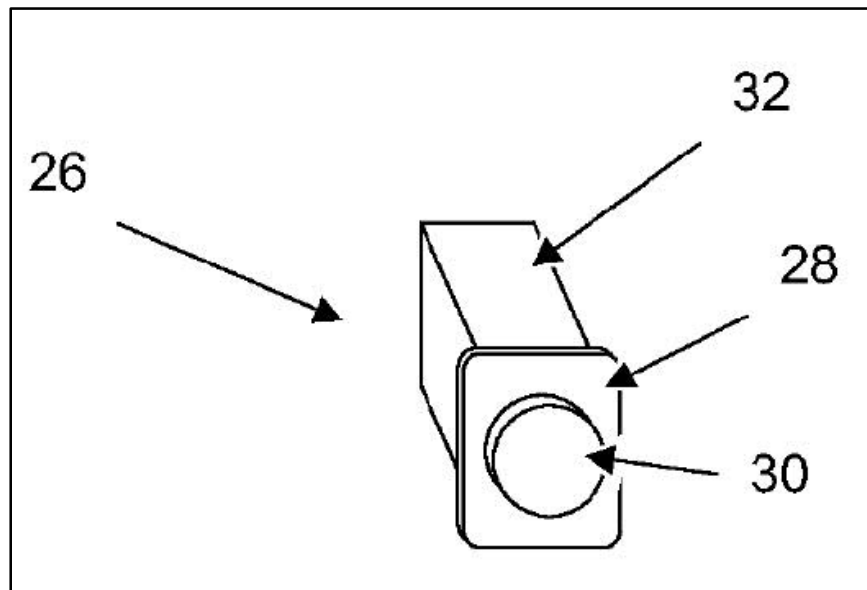
Ex. 23 (BRGEDEL000001507) (10 mL Pump Module)

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Ex. 29 (BRGEDEL000001261) (Inject Valve Module)

133. The panel members identified above plainly “separate the fluidics section from the non-fluidics section,” just the claim requires. Indeed, they are each interposed between the fluidics section and the non-fluidics section, just as illustrated in the Asserted Patents:



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Asserted Patents, Fig. 4a (element 28).

134. Note that I see no reason why the fact that certain of the modules have LEDs or displays integrated into their panel members takes them outside the scope of the claim language. For one, as discussed, the fact that these are non-fluidics components is not relevant since under the Court's claim construction, only the fluidics section cannot have non-fluidics components such as electronics, and the panel member is a different section in that it is neither a "fluidics section" nor a "non-fluidics section."

135. Mr. Bland testified that the portions I have identified as the claimed panel members is comprised of what Bio-Rad calls a "front plate" having an overlay affixed to the front plate portion on the external side of the system. Bland Tr. 151:4-155:21. Mr. Chapman testified as follows regarding the purpose of the faceplate and overlay:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

HIGHLY CONFIDENTIAL (TECHNICAL) - ATTORNEYS' EYES ONLY

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Chapman Tr. 386:13-389:1.

136. Mr. Chapman's testimony thus further demonstrates that the face plate/overlay structure that each of Bio-Rad's modules has separates the fluidics section from the non-fluidics section.

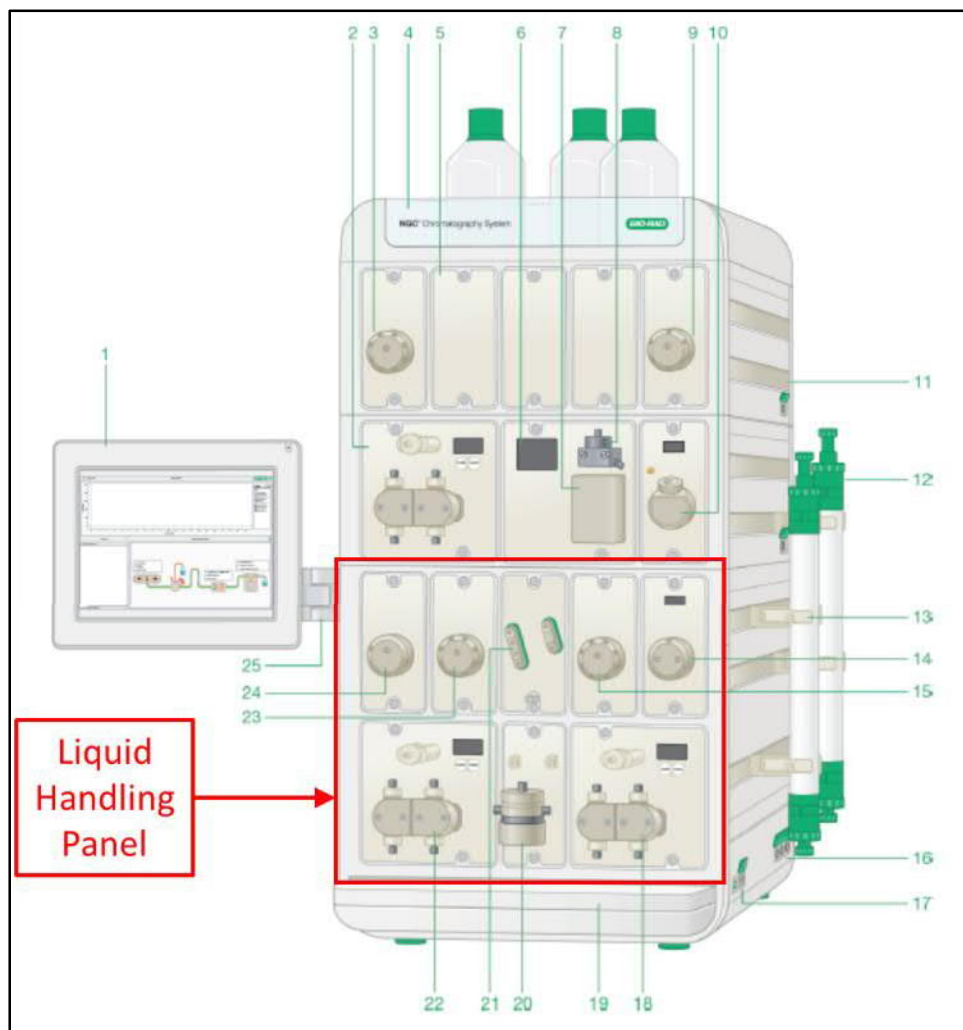
137. Thus, this claim element is met by all models of Bio-Rad's NGC system.

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- i. wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing

138. Each of Bio-Rad's NGC system models has a "liquid handling panel."

Bio-Rad's Instrument Guide shows this is present:





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Ex. 5, p. 22. As can be seen in the above illustration from Bio-Rad's documentation, the liquid handling panel has multiple "receiving positions." Note that a portion of the liquid handling panel is hidden by the panel members of the modules. The following illustration from Bio-Rad's Instrument Guide provides a view of a portion of the NGC liquid handling panel:



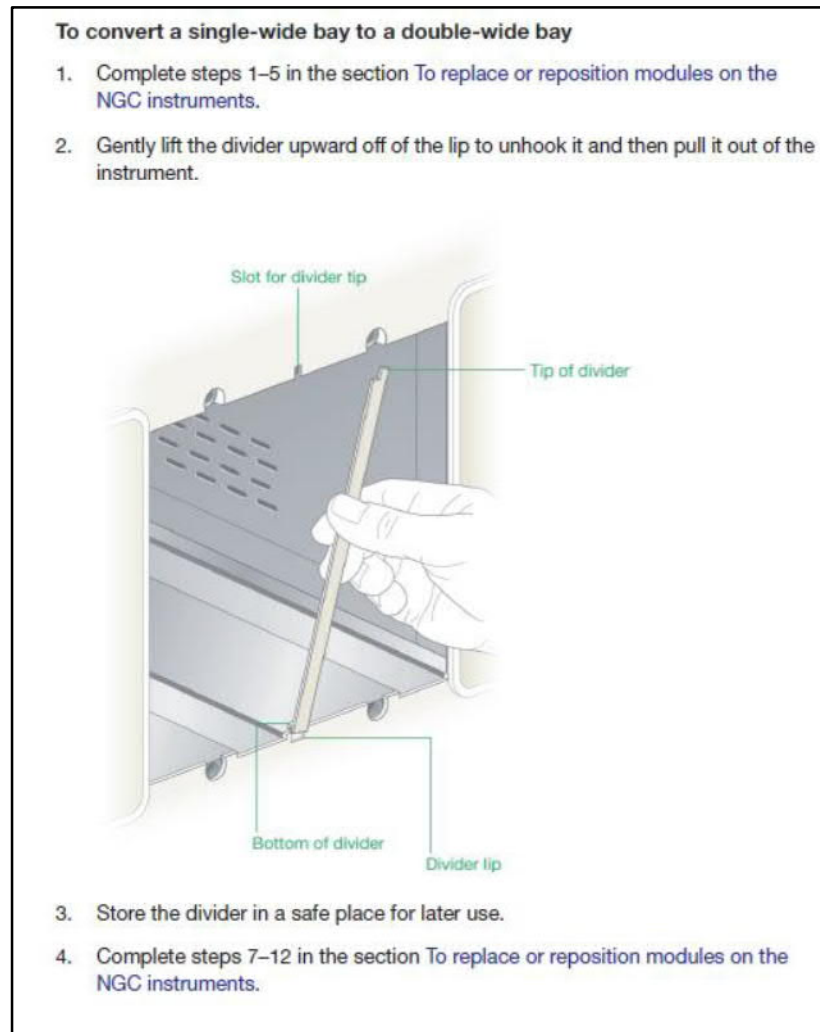
Ex. 5, p. 237. Another view is as follows:

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Ex. 5, p. 234. The below illustration shows how to convert a single-wide bay to a double-wide bay:

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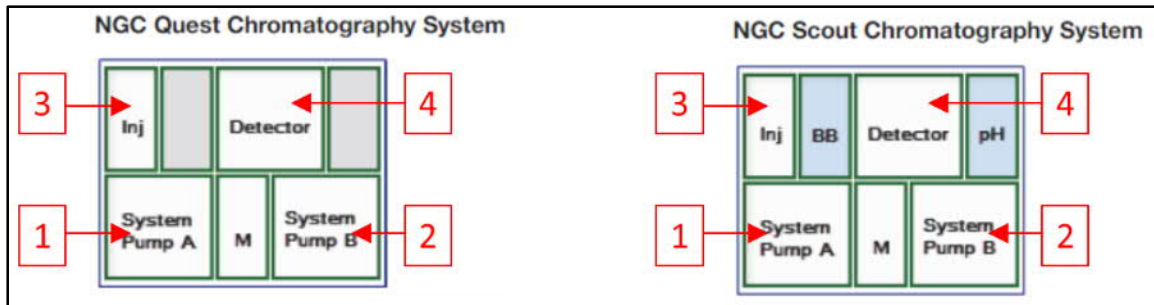


Ex. 5, p. 238.

139. The housing used in all models can accommodate up to ten modules and thus can have up to ten “component receiving positions,” which satisfies the “at least four” requirement. As I discussed above, the size of Bio-Rad’s “bays” can be changed to be single-wide or double-wide bays, meaning depending on Bio-Rad’s customer choice, the housing can accommodate as many as 10 modules (i.e., without

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using any double wide modules). In the Quest and Scout standard configurations, the following four positions in the below annotated version of figures from Bio-Rad's Instrument Guide are "component receiving positions":■



See Ex. 5, p. 90.

140. These four receiving positions are plainly arranged in a two dimensional array, just as the claim requires. The same is true for the receiving positions of the housing in the Discover and Discover Pro models.

141. Note the claim language only requires that the receiving positions be "adapted to receive said interchangeable modular components." By reciting that the receiving positions are "adapted to receive," the claim only requires that they be able to receive the interchangeable modular components.

142. As seen above, Bio-Rad's system pump modules, sample inject valve module, UV detector modules and pH valve modules are such that "when inserted,

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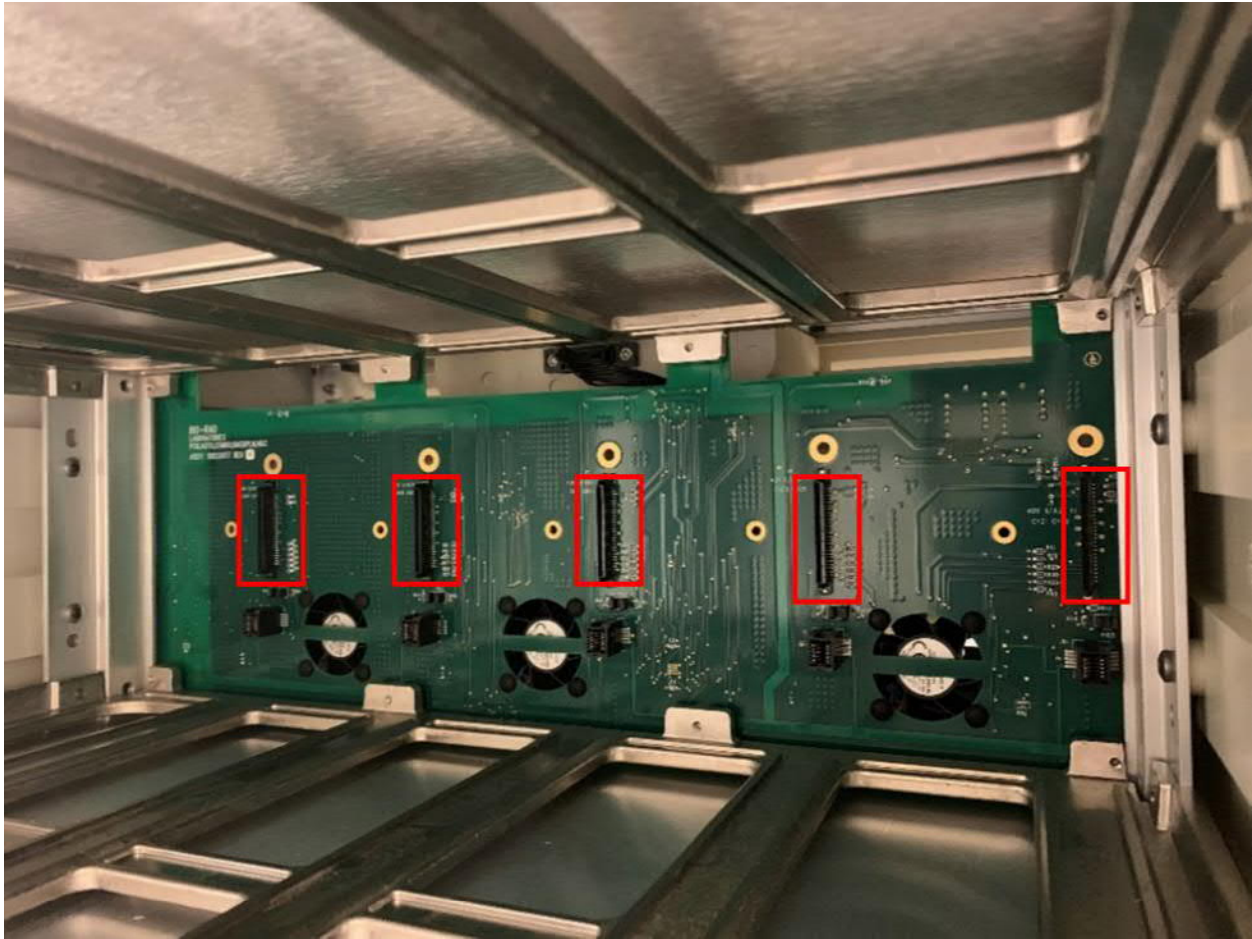
the fluidics section is external to the housing and the non-fluidics section is internal to the housing.”

143. Thus, this claim element is plainly present in all models of the NGC system.

- j. wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus**

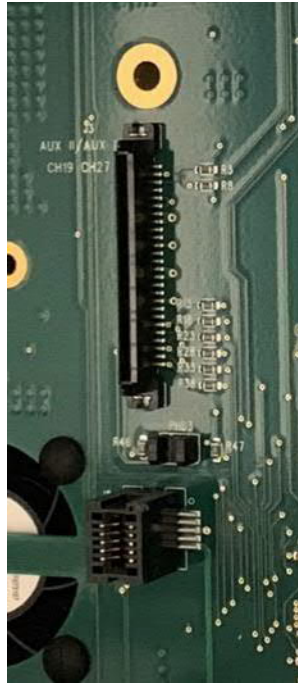
144. Each “receiving position” of Bio-Rad’s NGC system models has a “complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus.” As seen below in photograph taken by Cytiva, the backplane in the NGC system has connectors that receive and mate with the bus connectors on each module:

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145. Another photograph taken by Cytiva provides a closer view of one of the complementary connectors on the backplane of the NGC system:

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146. These connectors are plainly “complementary” since when a module is installed, the connector on the module is inserted into the connector on the backplane. Indeed, if the connector on the backplane were not a “complementary connector,” the connector on the module would not fit, and no connection could be made.

147. Bio-Rad’s NGC Instrument Guide states the following:

9. Place the module into the open bay and gently push it in as far as it will go.

**Note:** Each module has an alignment pin on the back to ensure that it aligns correctly with the main communication board.

Ex. 5, p. 235.

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148. The alignment pin on each module ensures that the connector on the module and the connector on the NGC backplane mate properly.

149. These complementary connectors in the NGC “connect[] the bus connector of the interchangeable modular component inserted therein to said system bus.” As discussed, the system bus in Bio-Rad’s NGC system is [REDACTED] As Mr. Bland testified, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

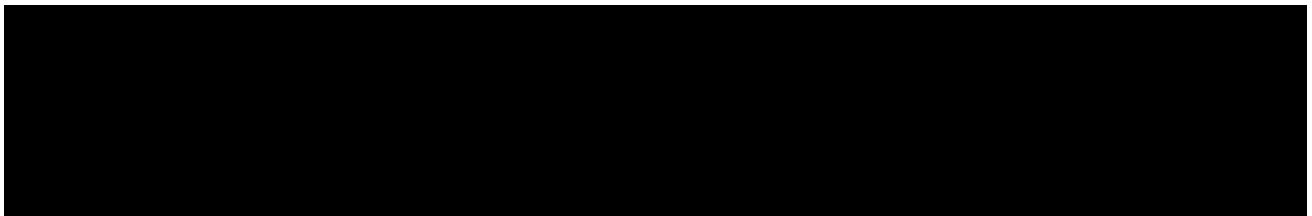
Bland Tr. 144:1-144:11. Thus, by inserting the bus connectors on the modules into the complementary connectors on the backplane inside the NGC, that connector is inserted in the system bus, just as the claim requires.



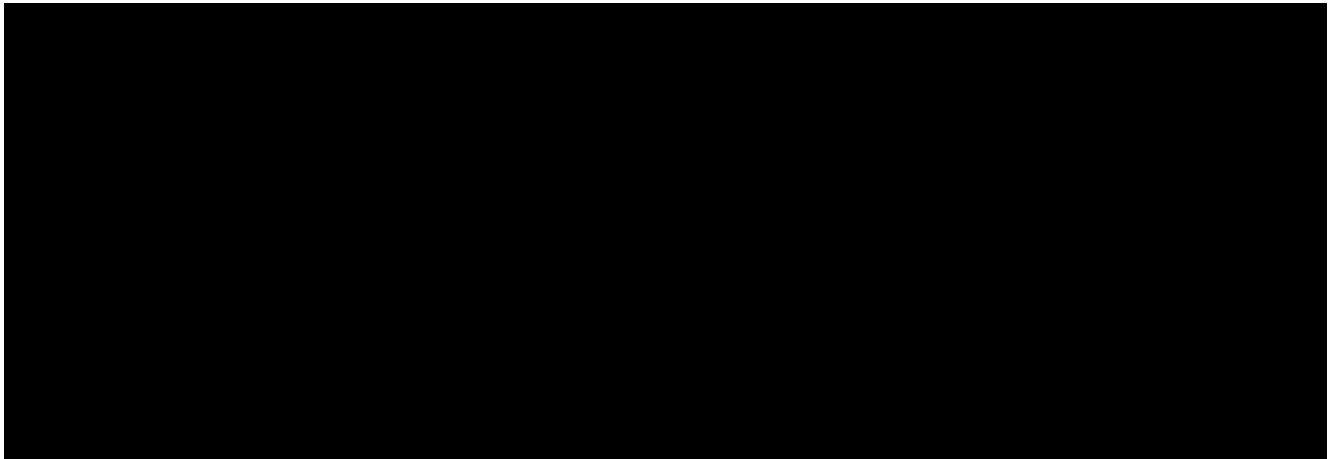
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- k. wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus;**

150. The “three or more fluid handling units arranged as interchangeable modular components” I identified above each have an “dedicated CPU unit.” As noted above, the parties agreed that CPU should be construed as “central processing unit,” which is what the abbreviation “CPU” stands for. The specifications for each demonstrate this:



Ex. 14 (BRGEDEL000450746) ( [REDACTED] )



Ex. 13 (BRGE0096081) ( [REDACTED] )

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151. As can be seen from the above excerpts, each of these Bio-Rad module specifications states: [REDACTED]

[REDACTED]

[REDACTED]

152. First, it is well known that microcontrollers include CPUs. Mr. Bland testified that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

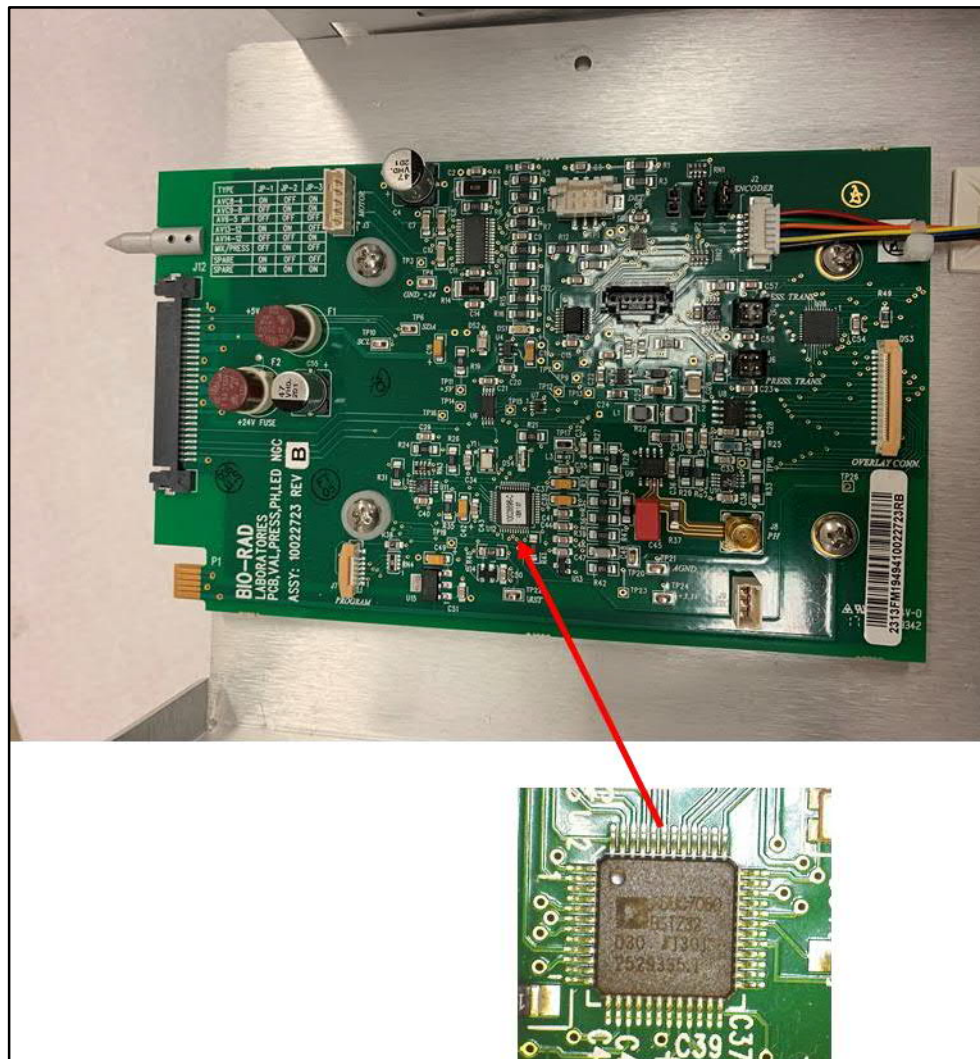
[REDACTED]

[REDACTED]

Bland Tr. 105:2-105:17.

153. Cytiva photographed the circuit board inside one of the modules of the NGC it has, which confirms that each module has a CPU:

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154. In the photo, you can see the markings for this part is for an ADC7060.

The datasheet for this component confirms that it has a CPU:

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**PROCESSOR REFERENCE PERIPHERALS  
INTERRUPT SYSTEM**

There are 15 interrupt sources on the ADuC7060/ADuC7061 that are controlled by the interrupt controller. All interrupts are generated from the on-chip peripherals, except for the software interrupt (SWI), which is programmable by the user. The ARM7TDMI CPU core recognizes interrupts as one of two types only: a normal interrupt request (IRQ) or a fast interrupt request (FIQ). All the interrupts can be masked separately.

Ex. 18 (GEHCDEL129737, at GEHCDEL129796).

155. Bio-Rad's internal firmware specifications further demonstrate that the

[REDACTED]

[REDACTED]

Ex. 17 (BRGEDEL98274)

156. The portions of specifications I excerpted above also demonstrate that [REDACTED] on each module allows "the interchangeable modular component to independently perform operations in response to instructions over the system bus." As discussed, the Bio-Rad specifications each state that [REDACTED]

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[REDACTED]

[REDACTED] This demonstrates that the CPU on each module “performs operations” since Bio-Rad’s documents unambiguously state that [REDACTED]

[REDACTED]

157. The claim language further requires that the CPUs “allow[] the interchangeable modular component to independently perform operations in response to instructions over the system bus.” This plainly happens. First, the language “independently perform operations” refers to the modules themselves, and thus requires that the particular module’s operations be independent from the operations of other modules installed in the system. This is further supported by the claim language reciting that the independent operations be performed “in response to instructions over the system bus.” A POSITA would understand this means that the CPU operates in conjunction with other processing devices in the system, and plainly does not mean that the in-module CPUs must operate completely by themselves. Such a reading of the claim would ignore the claim language and defy common engineering principles. Indeed, the fact that the specification describes use of a “master” control unit plainly would indicate to a POSITA that other processing devices are involved.

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158. At his deposition, Mr. Iovanni testified regarding the meaning of the word “independently” when questioned regarding Exhibit 4:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Iovanni Tr. 105:9-105:22. Mr. Bland testified that [REDACTED]

[REDACTED] (in the context of Exhibit 47, the system pump specification):

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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Bland Tr. 105:18-108:13. When questioned regarding the column switch valve module (Exhibit 50), Mr. Bland further testified that [REDACTED]

████████████████████

\_\_\_\_\_

10 of 10



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[REDACTED]



\_\_\_\_\_

[REDACTED]

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██████████

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\_\_\_\_\_

\_\_\_\_\_

Bland Tr. 129:2-130:16.

159. Mr. Iovanni's testified:

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Iovanni Tr. 105:9-105:22. Dr. Gale then states:

[REDACTED]

160. I note initially that I presented Mr. Bland's testimony as evidence of infringement, although it also supports the construction I have determined a POSITA would use here. I won't repeat all his testimony, but this one quote is pertinent:

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

161. Bland Tr. 107:13-108:13. Mr. Bland's agreement that the [REDACTED] is consistent with how I believe a POSITA would understand the term.

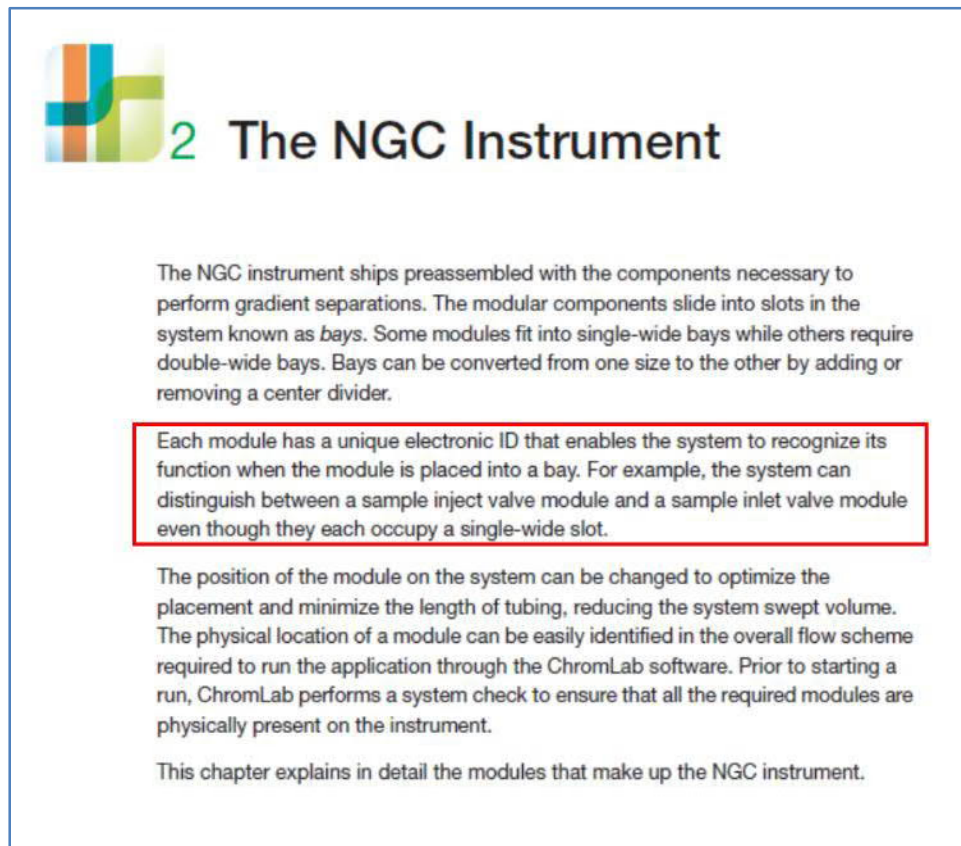
162. In addition, I have reviewed the declaration provided by Nenad Vukicevic, who reviewed portions of Bio-Rad's source code for the NGC system, and this confirms the documentation and testimony that Bio-Rad's interchangeable modular components independently perform operations "in response to instructions over the system bus." See e.g., Paragraphs 5-8, 10.

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163. In sum, this claim element is present in all models of the NGC system.

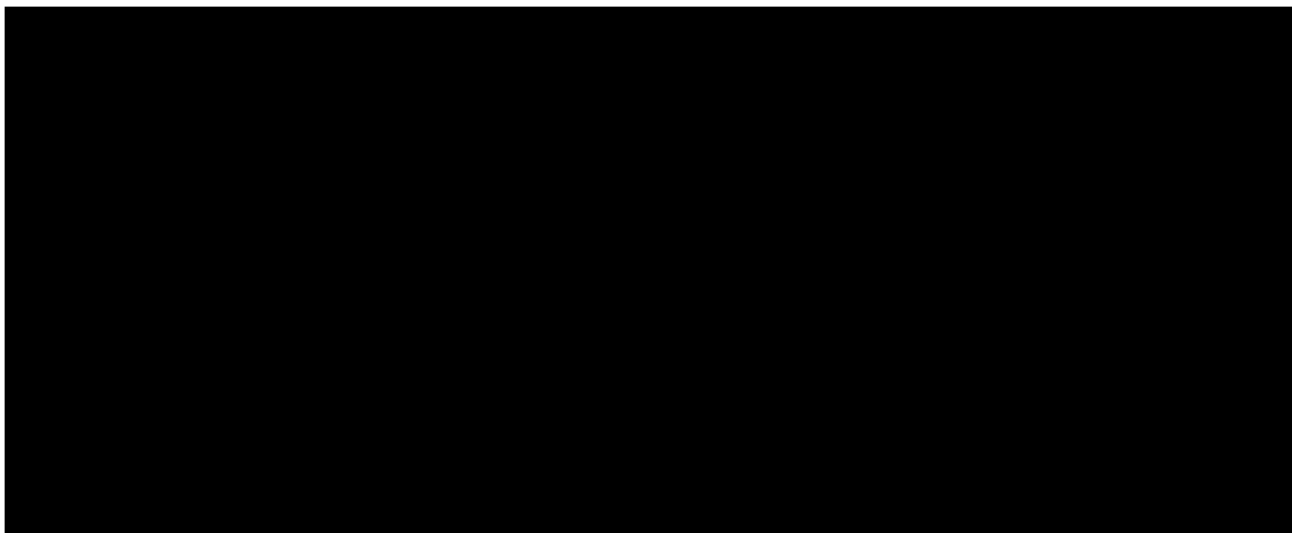
**I. wherein the master control unit is arranged to automatically identify interchangeable modular components;**

164. All models of the NGC system have a master control unit that “automatically identif[ies] interchangeable modular components.” The NGC Instrument Guide states:



Ex. 5, p. 19. This August 5, 2010 specification also demonstrates that this claim limitation is met:

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Ex. 12 (BRGEDEL401629).

165. Mr. Bland testified that this takes place as well:



Case 1:18-cv-01899-CFC-SRF Document 196-1 Filed 12/22/20 Page 114 of 1041 PageID #: 8275

[illegible]

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Bland Tr. 194:4-196:12.

166. I have also reviewed the Vukicevic declaration, where he shows this feature is present in Bio-Rad's source code, consistent with all of Bio-Rad's documentation and testimony. See Vukicevic, Paragraph 9.

167. In sum, this claim element is present in all models of the NGC system.

- m. wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least three of the pump, the sensor unit, and the fluid control valves are interchangeable modular components; and**

168. This claim element is present in all models of the NGC system.

169. The claim language asserts that the "housing is adapted to accommodate" a variety of different functional units, some of which must be "interchangeable modular components. The "adapted to accommodate" claim language only requires that the housing have the ability to have the listed items. In other words, for infringement to take place, the claim language does not require the listed items be present, but only that it is possible that the housing *can accommodate* them. Each model can plainly have the listed items:

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Table 9. NGC chromatography system configurations				
Module	NGC Quest	NGC Scout	NGC Discover	NGC Discover Pro
Sample injection valve	✓	✓	✓	✓
Single-wavelength UV and conductivity monitor (Available on the NGC Quest and NGC Scout systems only)	✓	✓		
Multi-wavelength UV/Vis and conductivity monitor (Available on all NGC systems)	✓	✓	✓*	✓*
System pumps A and B	✓	✓	✓	✓
Mixer	✓	✓	✓	✓
pH valve		✓	✓	✓
Buffer blending valve		✓	✓	✓
Column switching valve 1			✓	✓
Sample pump			✓	✓
Buffer inlet valves A and B			✓	✓
Third expansion tier			✓	✓
Table 9. NGC chromatography system configurations, continued				
Module	NGC Quest	NGC Scout	NGC Discover	NGC Discover Pro
Fourth expansion tier				✓
Sample inlet valve 1				✓
Outlet valve 1				✓
*Only the multi-wavelength UV/Vis detector is available in the NGC Discover series.				

Ex. 5, p. 87-88.

170. All NGC models can “accommodate” any of the above listed modules. For example, even the Quest, which, for example, does not come standard with a pH valve module, can accommodate one. Thus, a customer could purchase a Quest and decide to purchase a pH valve as well. Likewise, all NGC models can accommodate a column switch valve and an inlet valve. Any of these valve modules, along with



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the sample inject valve that comes standard with the Quest (and all other models) comprise fluid control valves of different configurations. Thus, all NGC models can “accommodate ... at least two fluid control valves of different configurations.”

171. All models come standard with system pumps, meaning that all models can “accommodate least one pump.”

172. All NGC models can also “accommodate ... at least one sensor unit.”

In the context of the Asserted Patents, UV module 4 is a sensor unit:

As is illustrated in FIG. 2, there are three large component positions e.g. for pump modules, one UV-sensor position and 9 standard component positions, e.g. for fluid control valves or the like.

5:57-61. All of Bio-Rad's NGC models comes standard with either a single wavelength UV detector module or a multi-wavelength UV detector module. Thus, all of Bio-Rad's NGC models can “accommodate ... at least one sensor unit.

173. Finally, this limitation also requires “at least three of the pump, the sensor unit, and the fluid control valves are interchangeable modular components.”

174. As discussed, the two system pump modules and the sample inject valve modules are interchangeable modular components. Thus, “at least three of the pump, the sensor unit, and the fluid control valves are interchangeable modular components,” as required by the claim.

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175. To the extent this claim element requires that the recited “sensor unit” also be an interchangeable modular component, Bio-Rad’s single and multi-wavelength UV detector modules qualify.

176. As discussed, the Technical Specification for NGC indicates that the

[REDACTED]

[REDACTED]

[REDACTED]

Ex. 12 (BRGEDEL401642). This plainly indicates that all modules, including UV detector modules, “can be inserted into and removed from positions in the housing” and “exchanged with another component,” just as the Court’s construction requires.

Mr. Bland testified as follows regarding this requirement:

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

HIGHLY CONFIDENTIAL (TECHNICAL) - ATTORNEYS' EYES ONLY

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

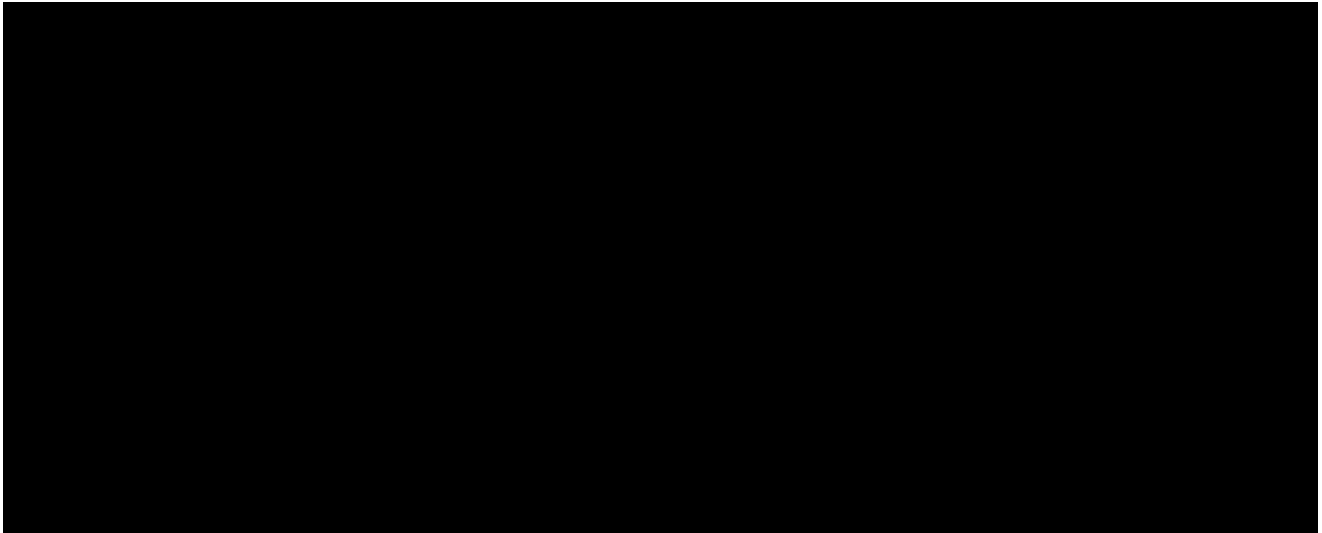
[REDACTED]

[REDACTED]

Bland Tr. 98:13-101:1.

177. This same document indicates that [REDACTED] was required for each module:

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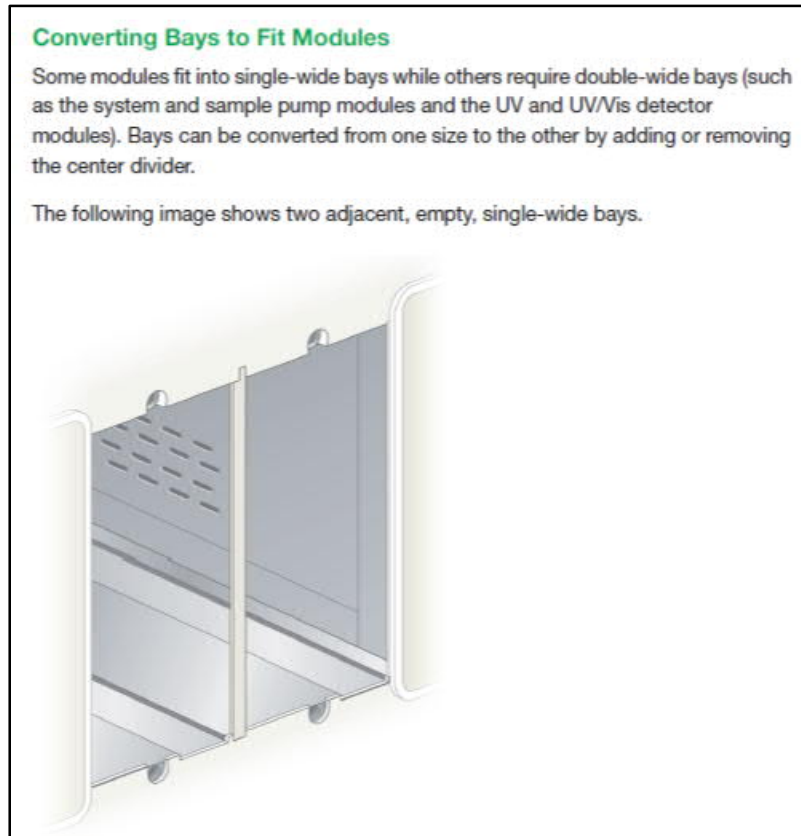
Ex. 12 (BRGEDEL401629).

178. Each of the modules have a standardized shape and size. In particular, the NGC has system “bays,” or positions, that can receive the modules, as I discussed above. In a section of Bio-Rad’s Instrument Guide entitled “Replacing or Repositioning Modules on the NGC Instruments,” Bio-Rad shows the following:

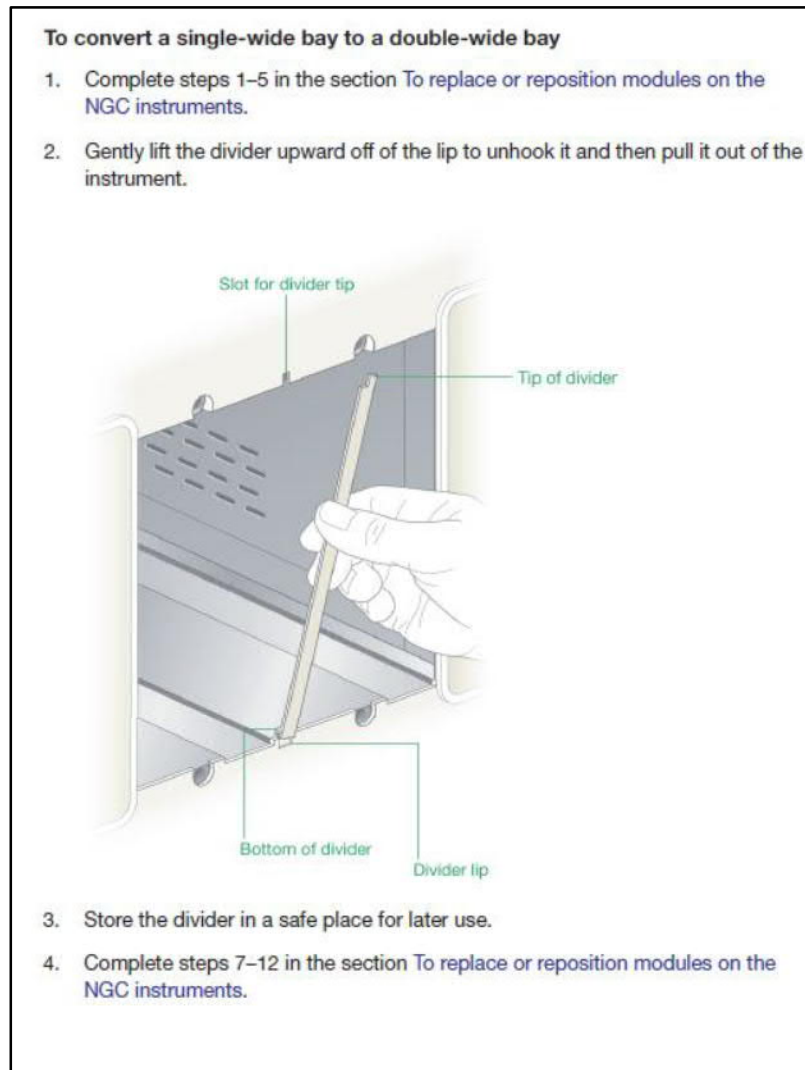


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Ex. 5, p. 234. The NGC can accommodate modules that are “single-wide” and “double-wide.” This is shown below:



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Ex. 5, pp. 236-238 (p. 236 not reproduced).

179. The UV detector modules are double-wide modules. This plainly demonstrates that these modules have a “standardized size and shape.”

180. Finally, by having these standard sized bays, the NGC system allows the module “to be exchanged with another component.” Bio-Rad’s Instrument

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Guide makes that clear, as it indicates that a person can replace or reposition modules:

**Replacing or Repositioning Modules on the NGC Instruments**

**WARNING!** Disconnect power to the NGC instrument before removing or repositioning any module. Do not attempt to service any component on the NGC instrument unless noted in this manual. Contact Bio-Rad for service requests.

**WARNING!** To reduce the chance of liquid seeping into the instrument, all open bays must be filled with the NGC Blank module (catalog #788-4005). The NGC instrument will not operate if it detects a slot without a module inserted.

**To replace or reposition modules on the NGC instruments**

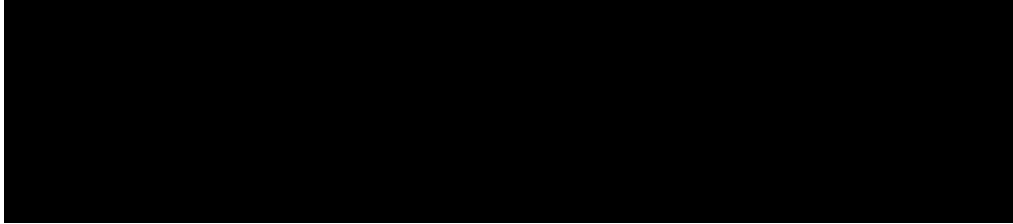
1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. If necessary, disconnect all tubing lines to and from the module that you plan to replace or reposition.
3. Loosen the captive screws on the front of the installed module.
4. Firmly grasp both screws on the module and pull it forward out of its bay.

See Ex. 5, p. 233. See also *Id.* at 234-239.

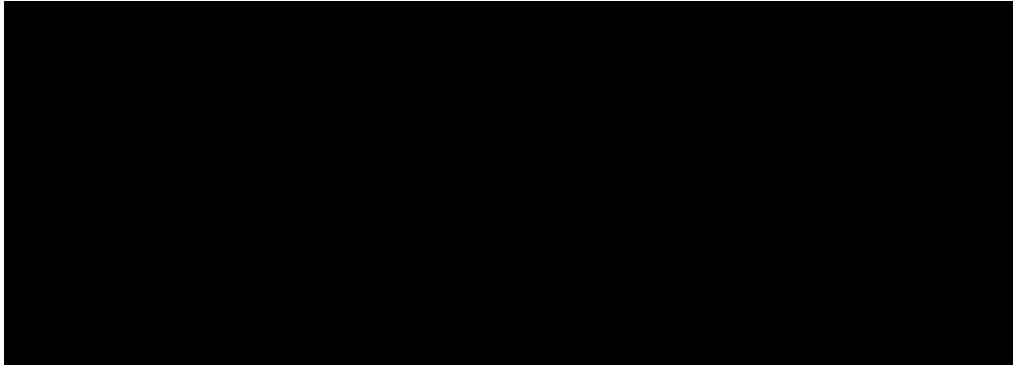
181. The UV detector module has a fluidics section, a non-fluidics section, and a panel member. The specifications for the UV Detector modules specify that they have a “fluidics section” because they state that



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Ex. 20 (BRGEDEL000281538) ([REDACTED])

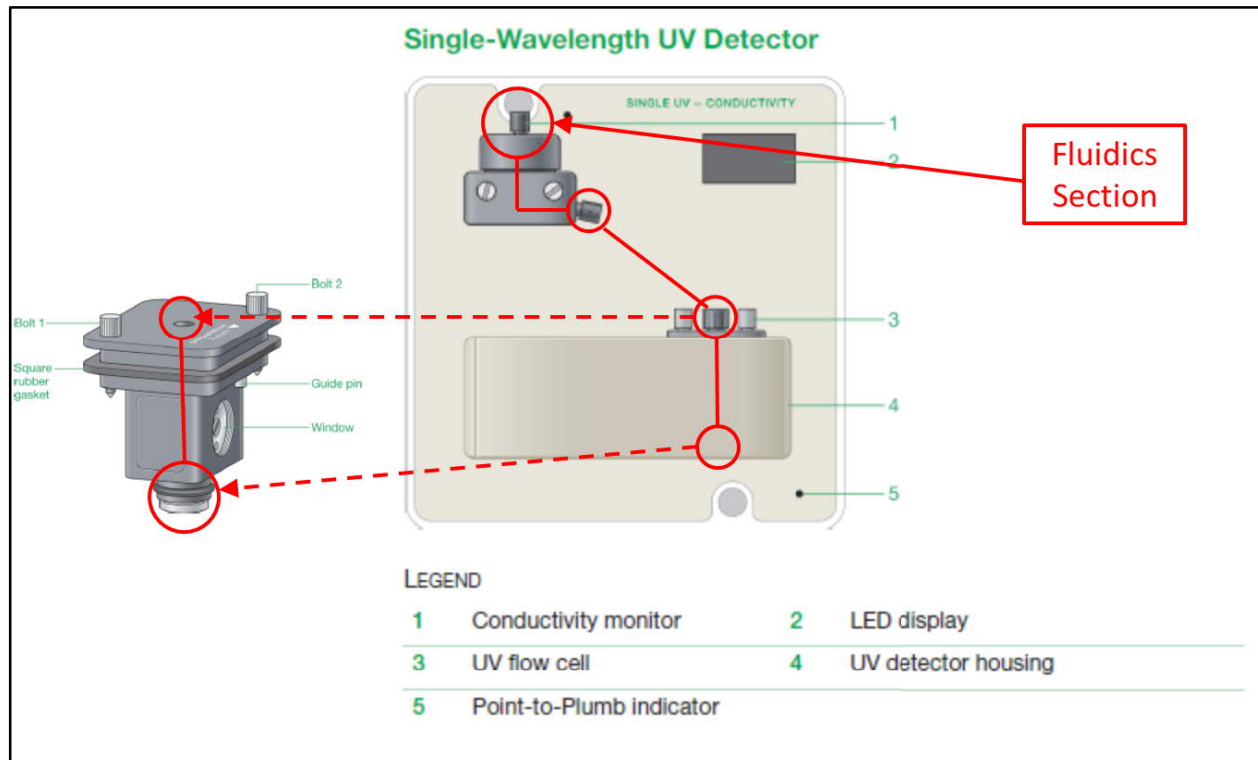


Ex. 19 (BRGEDEL000282560) ([REDACTED]).

182. Mr. Chapman testified that these specifications were met for the single wavelength detector module (Chapman Tr. 532:4-533:13), and the multi-wavelength UV detector (Chapman Tr. 533:15-534:17).

183. The fluidics section for the single wavelength UV detector module used in the NGC system is as follows:

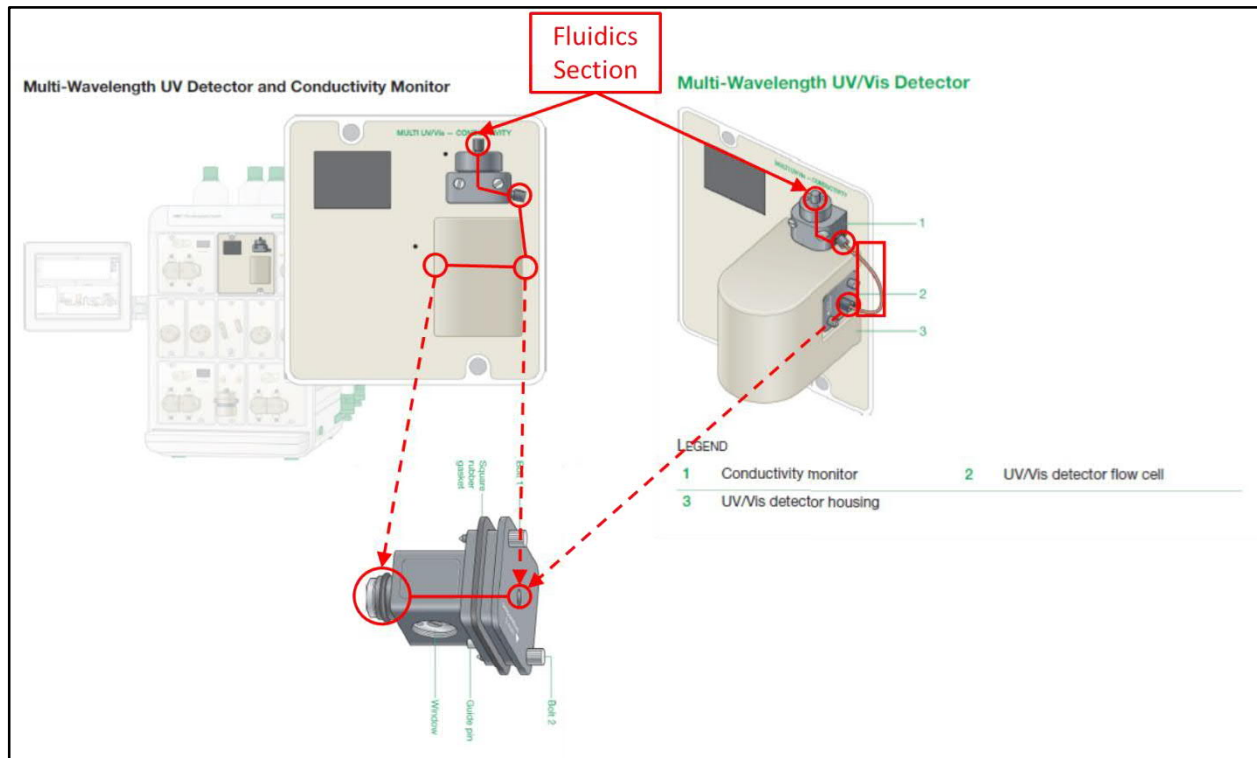
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Ex. 5, p. 67, 205.

184. The fluid handling section for the multi-wavelength UV detector module used in the NGC system is as follows:

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Ex. 5, p. 66, 69, 205.

185. As is seen, the fluidics section of each of these modules include fluidic components like tubing, tubing inputs and outputs, as well as a flow cell.

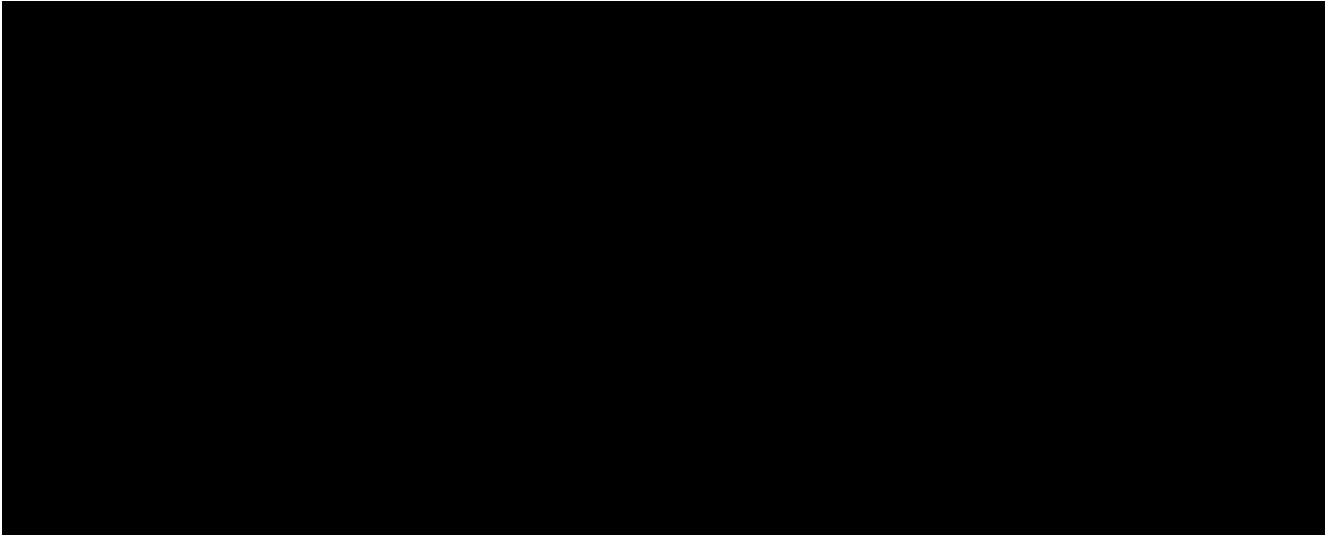
186. The Court's construction also requires that the fluid handling section *"not include non-fluidics components."* None of the fluidics portions I have identified above contain non-fluidics components. They are all involved in transmission of fluids, e.g., tubing, flow cells, tubing inputs and outputs, etc.

187. Any non-fluidics components located externally are not a part of the claimed fluidics section. Indeed, as discussed, the Court explicitly stated at the claim

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construction hearing that there can be electronics external to the housing but not in the fluid handling section. Markman Tr. 97:16-25. Likewise, the Court also said each module can have more than just a fluid handling section and a non-fluidics section. *See e.g., id.*, at 100:14-23 and 103:8-13.

188. The fluidics section of the single wavelength UV detector module is as follows:



Ex. 16 (BRGEDEL317456, BRGEDEL317558).

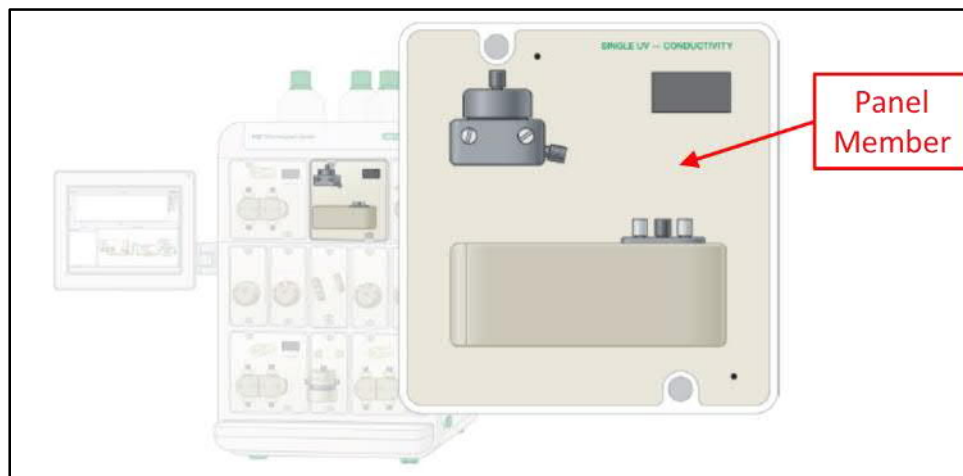
189. The fluidics section of the multi-wavelength UV detector module is as follows:

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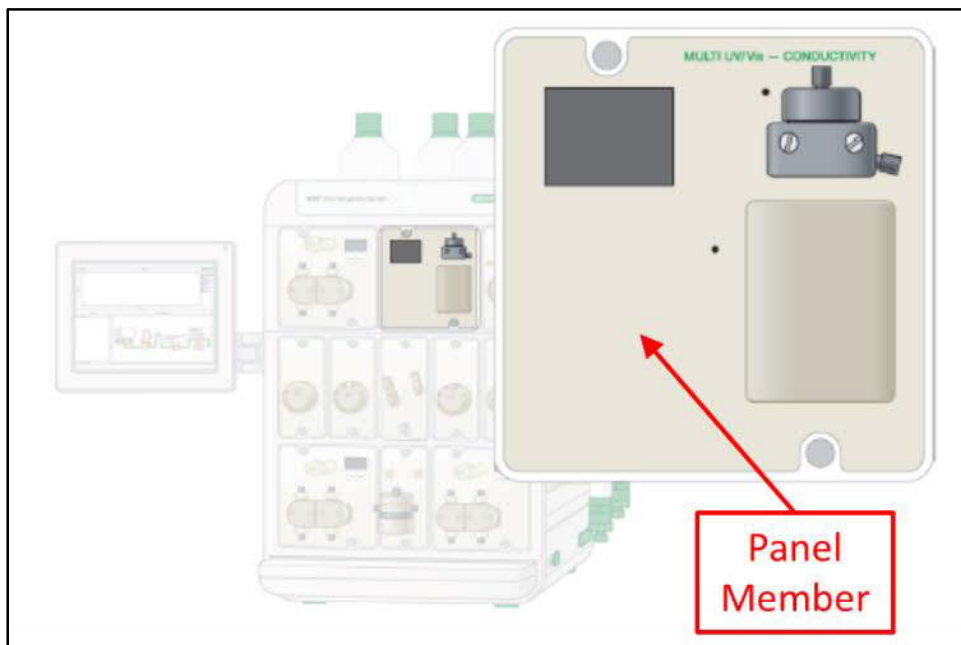
Ex. 16 (BRGEDEL317458-BRGEDEL317459, BRGEDEL317559).

190. Finally, both the single and multi-wavelength UV monitor module have panel members:



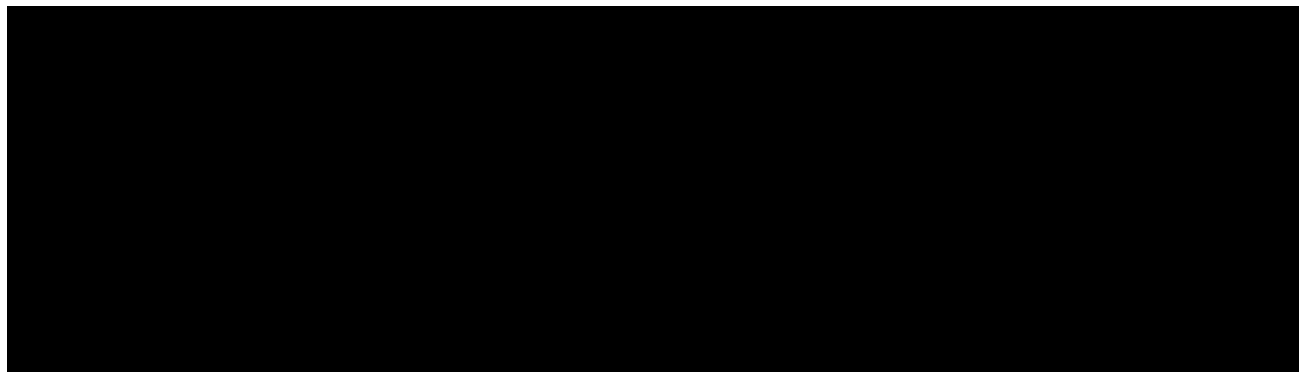
Ex. 5, p. 66.

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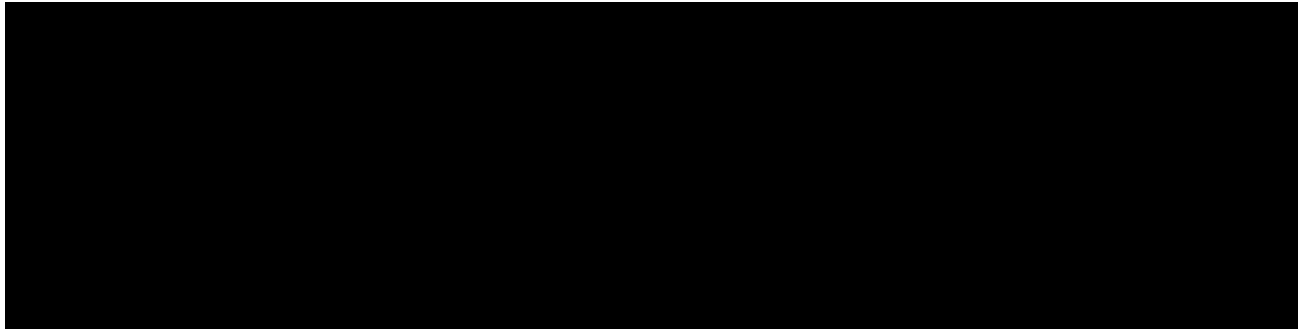
Ex. 5, p. 66.

191. Finally, each UV monitor module has a CPU.



Ex. 20 (BRGEDEL000281532) ( )

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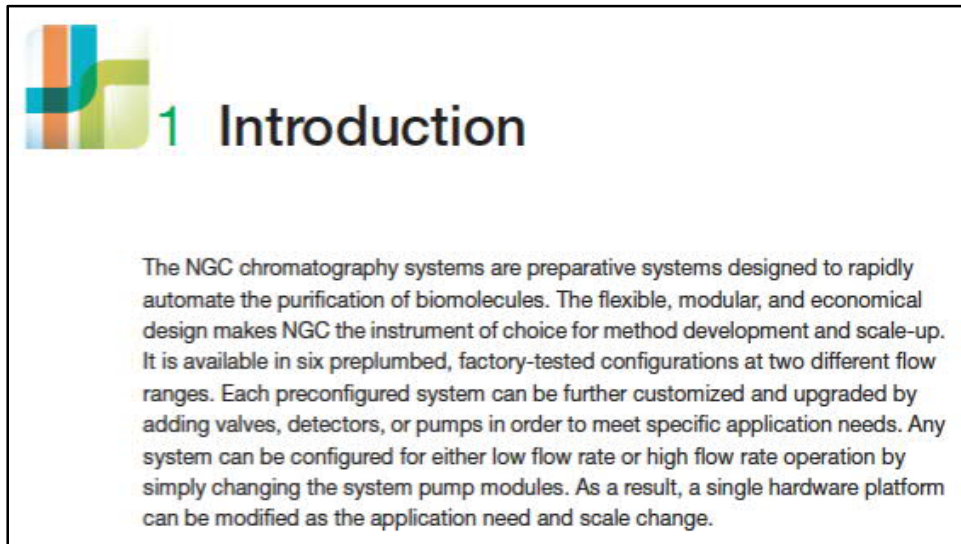
Ex. 19 (BRGEDEL000282542) ( [REDACTED] )

192. Thus, the element is met, and all models of the NGC system infringe claim 1.

**n. wherein the system is capable of performing automated liquid chromatography**

193. All models of Bio-Rad's NGC system are "capable of performing automated liquid chromatography." First, all models perform liquid chromatography. Likewise, all NGC models are capable of performing "automated" liquid chromatography:

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Ex. 5, p. 11. As this Bio-Rad document (Instrument Guide), the NGC system “rapidly automates” purification of biomolecules. Thus, a POSITA would understand that the NGC system is an automated liquid chromatography system.

194. In sum, all Bio-Rad NGC models infringe claim 1 of the ’420 patent.

**B. ’589 Patent**

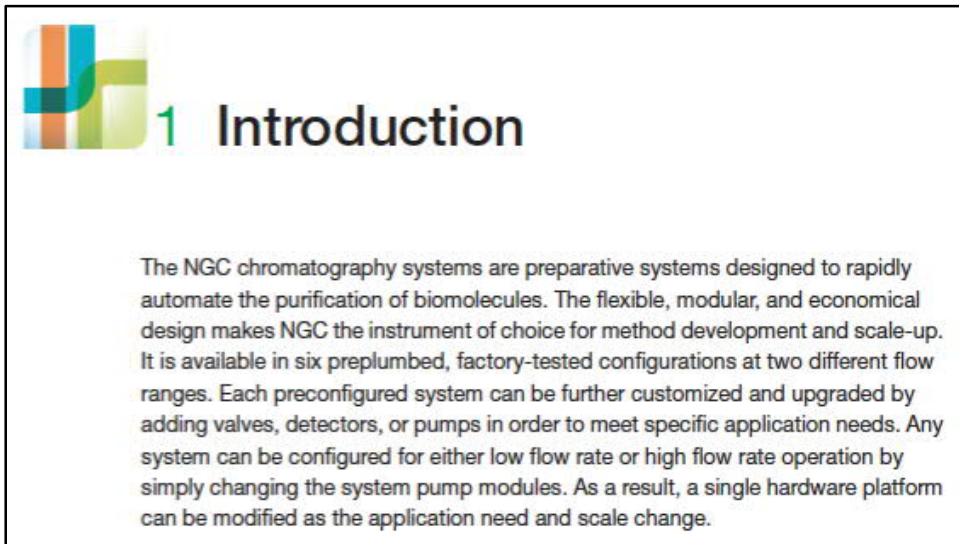
**1. Claim 1**

**a. “An automated liquid chromatography system comprising:**

195. Bio-Rad’s NGC system is an “automated liquid chromatography system. First, there can really be no dispute that Bio-Rad’s NGC is a “liquid chromatography system,” as its documents are replete with statements saying as such. One example is in the NGC Instrument Guide:



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Ex. 5, p. 11. Note that this document not only states that the NGC system is a liquid chromatography system, but it also notes that the NGC system “rapidly automates” purification of biomolecules. Thus, a POSITA would understand that the NGC system is an automated liquid chromatography system.

196. At her deposition, Dr. Mavandadi [REDACTED]

[REDACTED]

[REDACTED]

See Ex. 6

(BRGE00065119). When asked about this at her deposition, Dr. Mavandadi testified that [REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

Mavandadi Tr. 106:5-15.

197. This is plainly the case with the NGC system. Indeed, according this

[REDACTED]

document of Exhibit 6. Thus, the NGC system is plainly an “automated liquid chromatography system.”

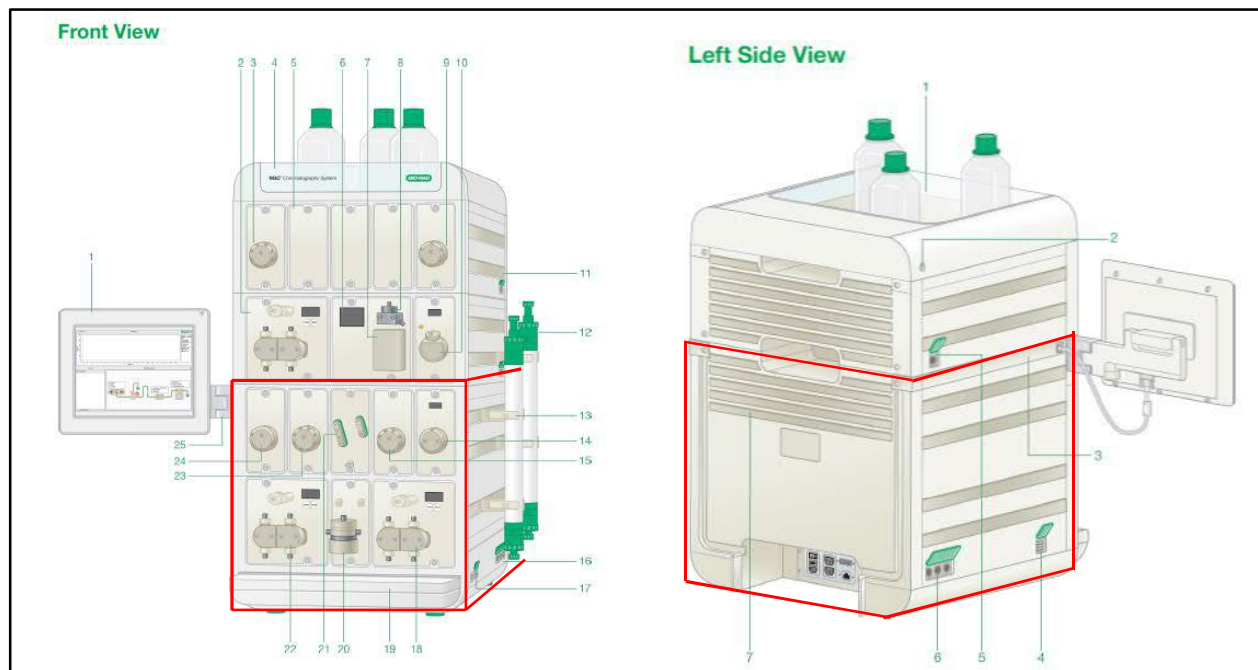
198. Moreover, automated liquid chromatography systems must have certain components to perform liquid chromatography, including at least an injection valve, a suitable pump, an inline detector that can measure the relevant characteristics of the liquid exiting the chromatography column, and control software for processing, displaying, and/or storing the results, which operate without manual intervention.

199. There is no dispute that Bio-Rad’s NGC system has each of these. I will discuss these in more detail below, but as will be seen, all Bio-Rad NGC models come standard with a sample inject valve module (Ex. 5, pp. 28, 87), two system pump modules (Ex. 5, pp. 28, 87), and a UV monitor module (Ex. 5, pp. 65-70, 87).

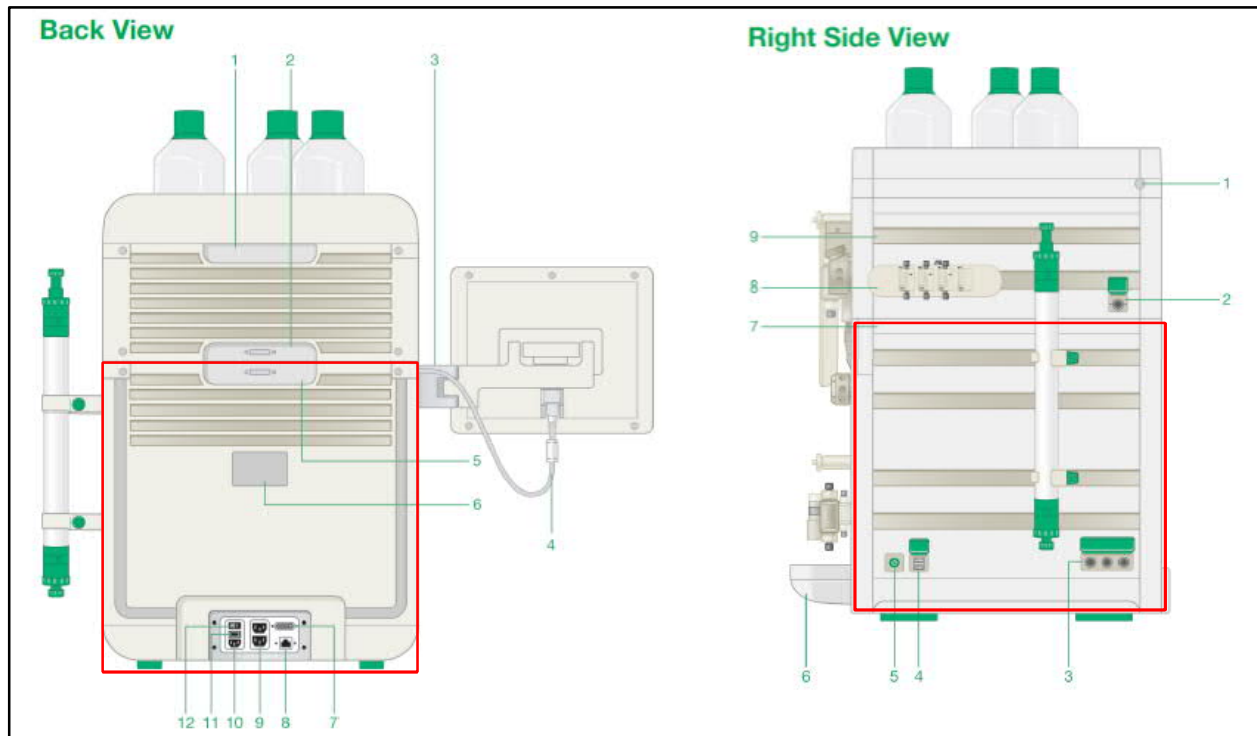
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**b. “a housing unit and”**

200. The NGC system plainly has a housing unit. The following two figures, which are annotated to show the housing, come from Bio-Rad's NGC Instrument Guide:”



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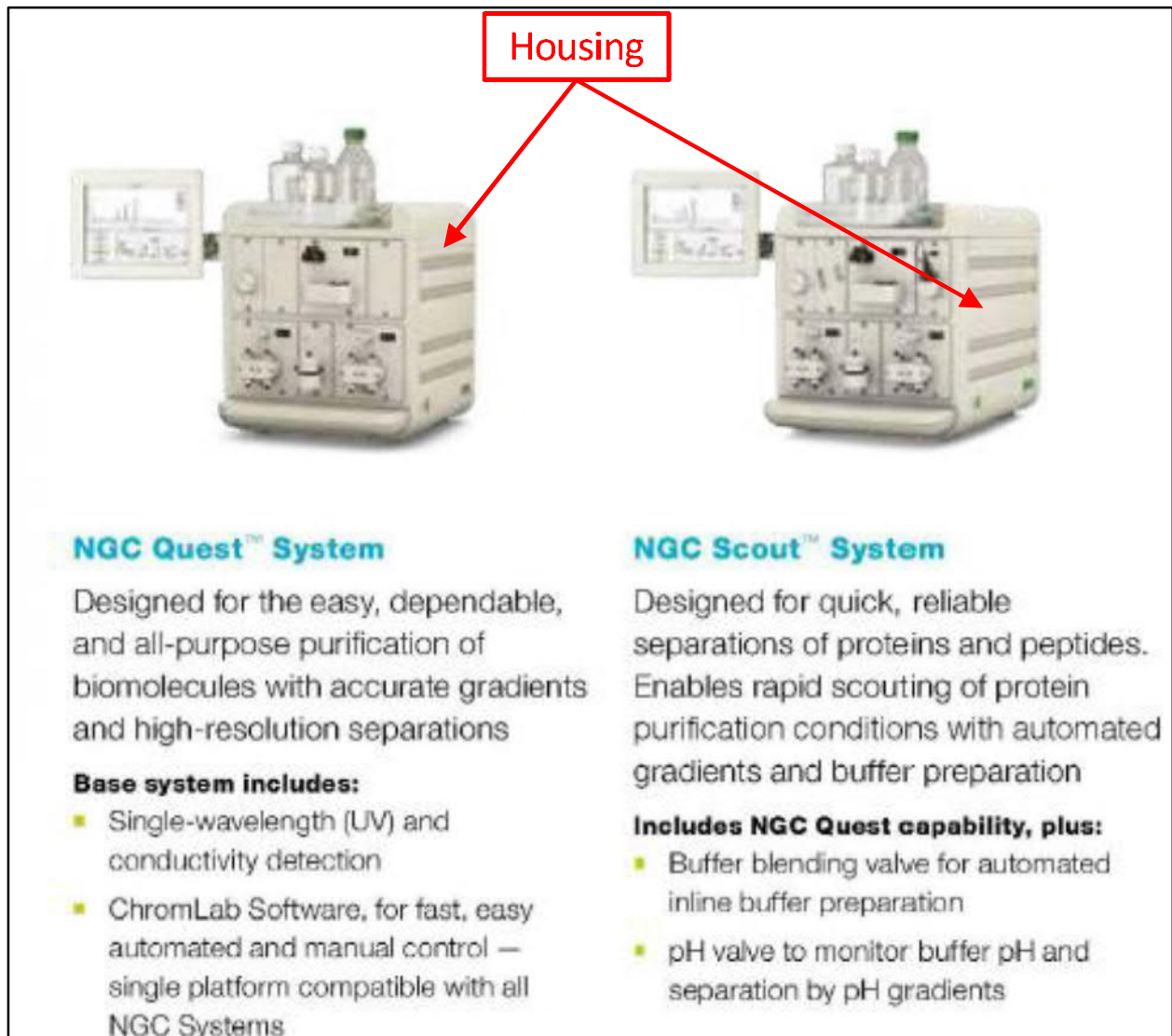


Ex. 5, p. 22, 24-26.

201. The “housing” is annotated in red. Note that the front view appears to depict a Discover Pro system, as it shows two expansion housings placed on top of the main enclosure. The remaining views appear to show a Discover system since they each show the NGC system with a single expansion housing stacked on the main housing.

202. Exhibit 21, a Bio-Rad marketing document, shows a good view of the Quest and Scout systems. A portion is reprinted below and points to the housing:

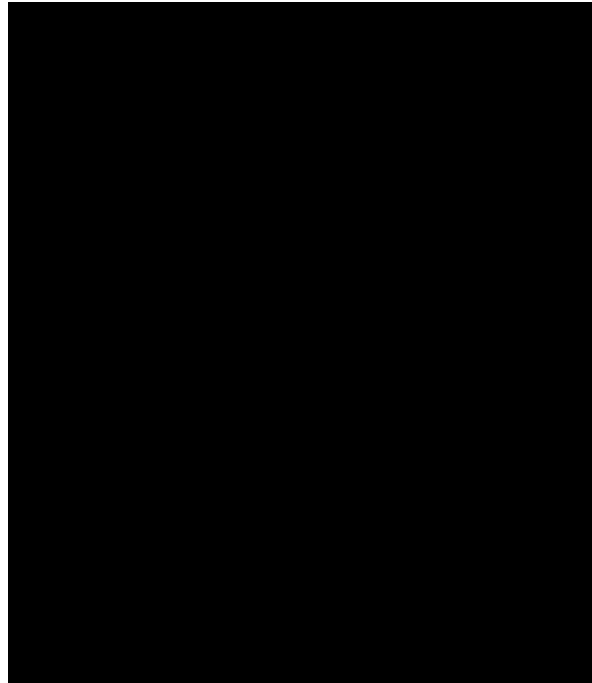
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Ex. 21, p. 3.

203. The “Assembly Procedure For Quest 10 Chrom 10 System NGC,” Bates No. BRGEDEL1541-1565 provides additional information:

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Ex. 24 (BRGEDEL000001591).

204. Exhibit 12 is the Technical Specification for the Next Generation Chromatography System. [REDACTED]

[REDACTED]

[REDACTED] BRGEDEL401625.

205. Mr. Iovanni testified that [REDACTED]

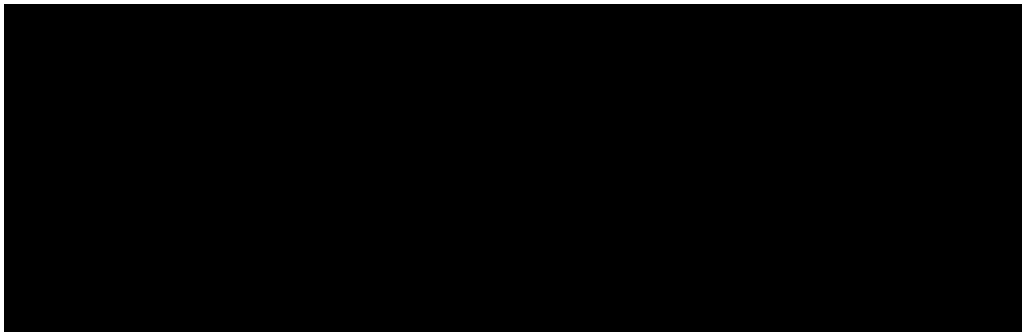
[REDACTED]. Iovanni Tr. 216:20-217:3. Ex. 12

contains the following entry as a specification for the NGC:

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BRGEDEL401628. This document further demonstrates that the NGC system has a housing:



BRGEDEL401629. Mr. Bland testified that this entry refers to the housing of the NGC:



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[REDACTED]

Bland Tr. 86:2-86:17.

206. The hardware specification for the NGC's Primary system Enclosure (Ex. 11), further demonstrates that the NGC systems include a "housing:"

[REDACTED]

Ex. 11 (BRGEDEL445194). Mr. Chapman testified that this document reflects a housing as well:

[REDACTED]



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[REDACTED]

[REDACTED]

[REDACTED]

Chapman Tr. 541:6-541:22.

207. In sum, this claim element is plainly present in all NGC models.

**c. “at least four modular fluid handling units”**

208. All NGC models include “at least four modular fluid handling units.”

209. As discussed, the Court construed “modular fluid handling units” to be a *“fluid handling unit that has a standardized size and shape that allows it to be exchanged with another fluid handling unit.”*

210. As discussed above, each NGC model can include the following modules:

	Quest	Scout	Discover	Discover Pro
1	System Pump	System Pump	System Pump	System Pump
2	System Pump	System Pump	System Pump	System Pump
3	Sample Inject Valve	Sample Inject Valve	Sample Inject Valve	Sample Inject Valve

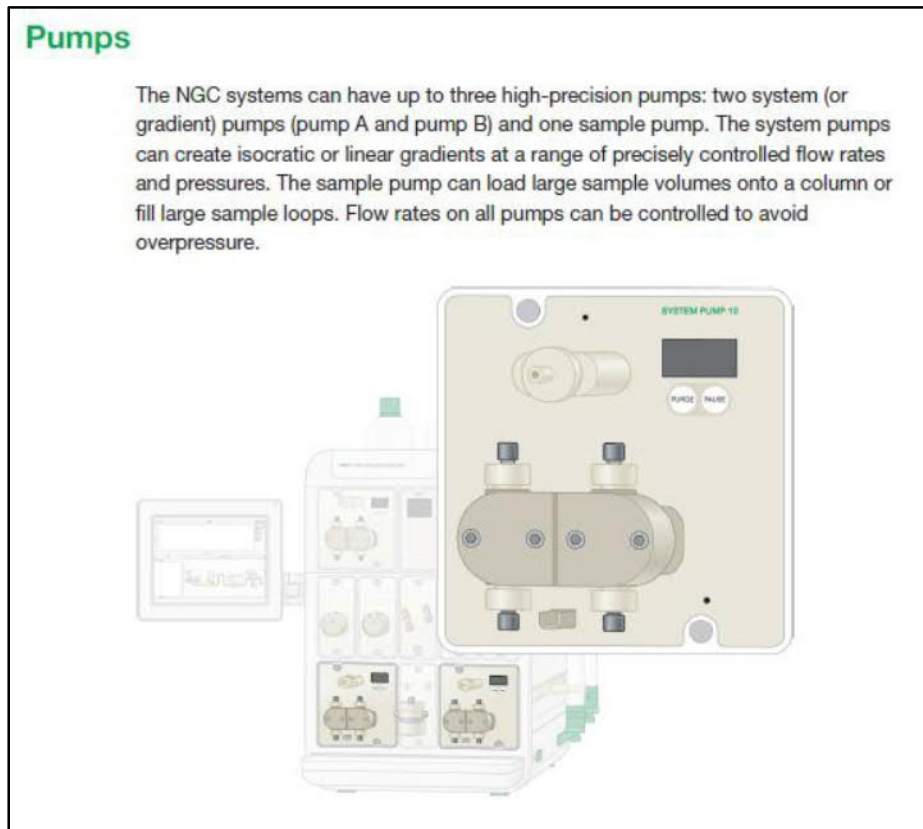
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	<b>Quest</b>	<b>Scout</b>	<b>Discover</b>	<b>Discover Pro</b>
4	UV Detector	UV Detector	UV Detector	UV Detector
5		pH Valve	pH Valve	pH Valve
6			Column Switch Valve	Column Switch Valve
7			Sample Pump	Sample Pump
8			Buffer Inlet Valve	Buffer Inlet Valve
9				Sample Inlet Valve
10				Outlet Valve

211. At a minimum, each of the two system pump modules, sample inject valve module and UV monitor modules are “modular fluid handling units.”

212. Bio-Rad’s Instrument Guide illustrates system pump modules:

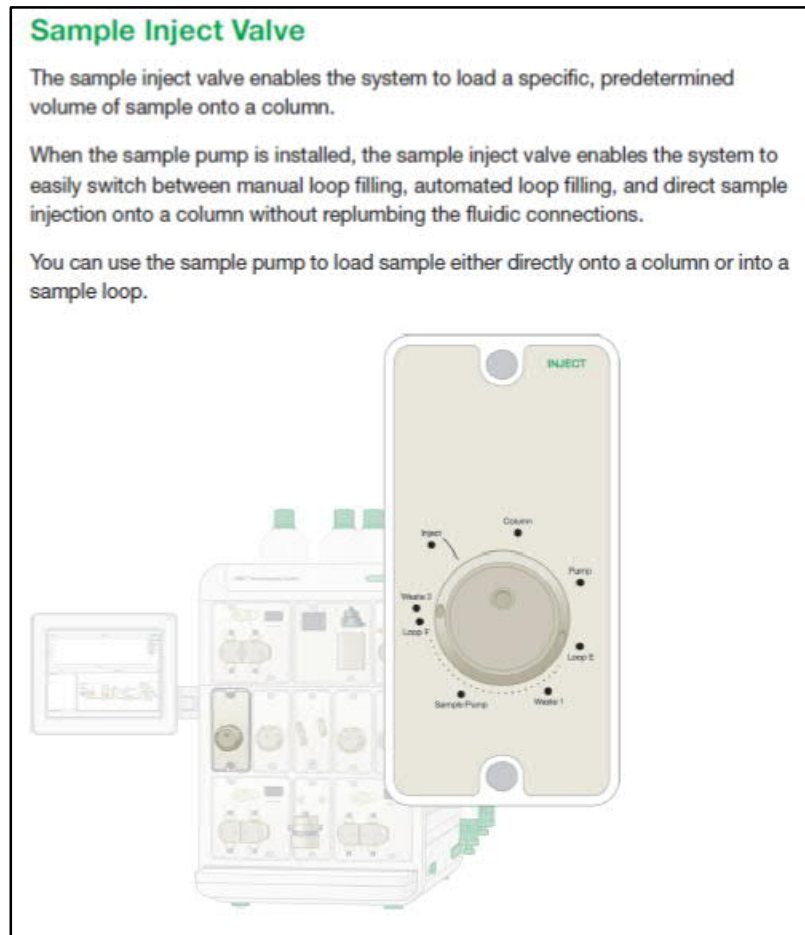
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Ex. 5, p. 28.

213. Bio-Rad's Instrument Guide illustrates the sample inject valve module:

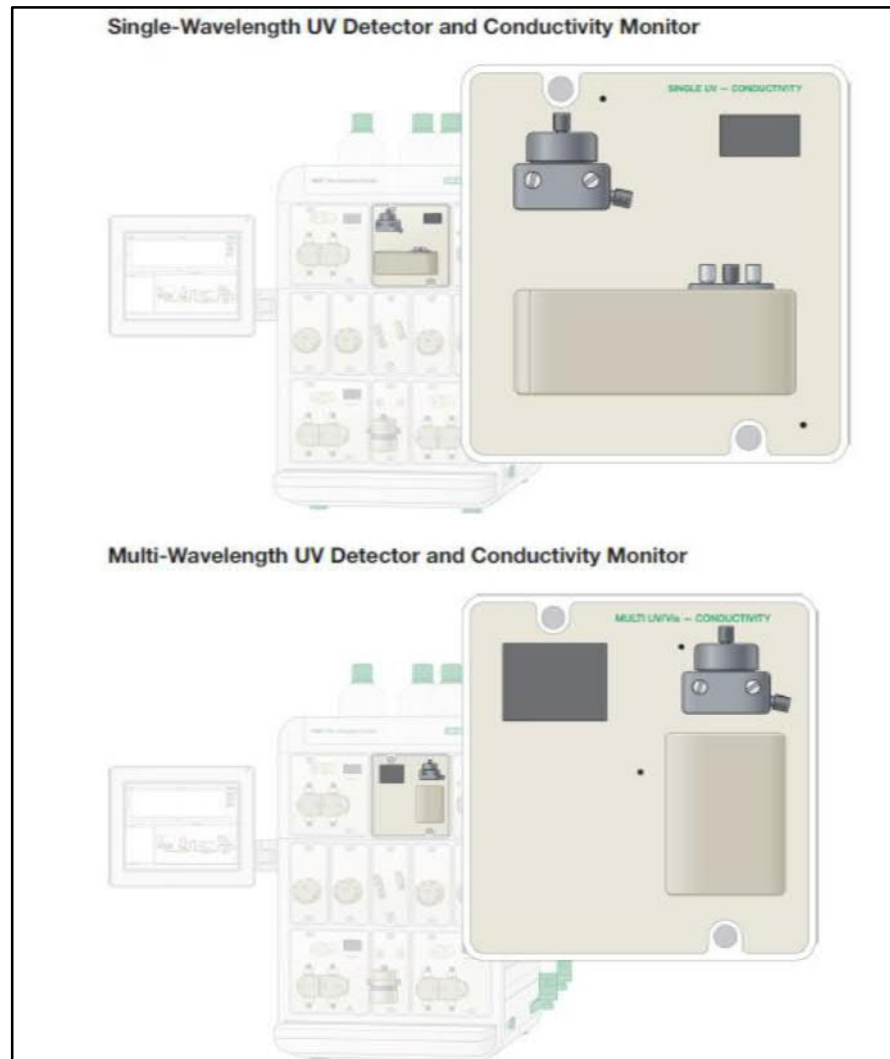
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Ex. 5, p. 37.

214. Bio-Rad's Instrument Guide illustrates UV Detection modules. The single wavelength and multi-wavelength detectors are illustrated as follows:

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Ex. 5, p. 66.

215. These modules, like all the NGC modules, can be inserted and removed, functionality required for them to have the ability to “be exchanged with another fluid handling unit,” which the Court’s construction requires:

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## 2 The NGC Instrument

The NGC instrument ships preassembled with the components necessary to perform gradient separations. The modular components slide into slots in the system known as *bays*. Some modules fit into single-wide bays while others require double-wide bays. Bays can be converted from one size to the other by adding or removing a center divider.

Each module has a unique electronic ID that enables the system to recognize its function when the module is placed into a bay. For example, the system can distinguish between a sample inject valve module and a sample inlet valve module even though they each occupy a single-wide slot.

The position of the module on the system can be changed to optimize the placement and minimize the length of tubing, reducing the system swept volume. The physical location of a module can be easily identified in the overall flow scheme required to run the application through the ChromLab software. Prior to starting a run, ChromLab performs a system check to ensure that all the required modules are physically present on the instrument.

This chapter explains in detail the modules that make up the NGC instrument.

*Id.*, p. 19. The Technical Specification for NGC indicates that [REDACTED]

[REDACTED]:

[REDACTED]

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Ex. 12 (BRGEDEL401642). This plainly indicates that all modules, including pump modules, sample inject valve modules, UV detector modules, and pH valve modules, “can be inserted into and removed from positions in the housing” and “exchanged with another component,” just as the Court’s construction requires. Mr. Bland testified as follows regarding this requirement:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

HIGHLY CONFIDENTIAL (TECHNICAL) - ATTORNEYS' EYES ONLY

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



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[REDACTED]

Bland Tr. 98:13-101:1.

216. This same document indicates that [REDACTED] was required for each module:

[REDACTED]

Ex. 12 (BRGEDEL401629).

217. Each of the modules have a standardized shape and size. In particular, the NGC has system “bays,” or positions, that can receive the modules. This is seen in the excerpt from NGC Instrument Guide (Ex. 5) I pasted above (p. 19). This same document illustrates this in more detail. In a section of the Instrument Guide entitled “Replacing or Repositioning Modules on the NGC Instruments,” Bio-Rad shows the following:

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Ex. 5, p. 234. The NGC can accommodate modules that are “single-wide” and “double-wide.” This is shown below:

HIGHLY CONFIDENTIAL (TECHNICAL) - ATTORNEYS' EYES ONLY

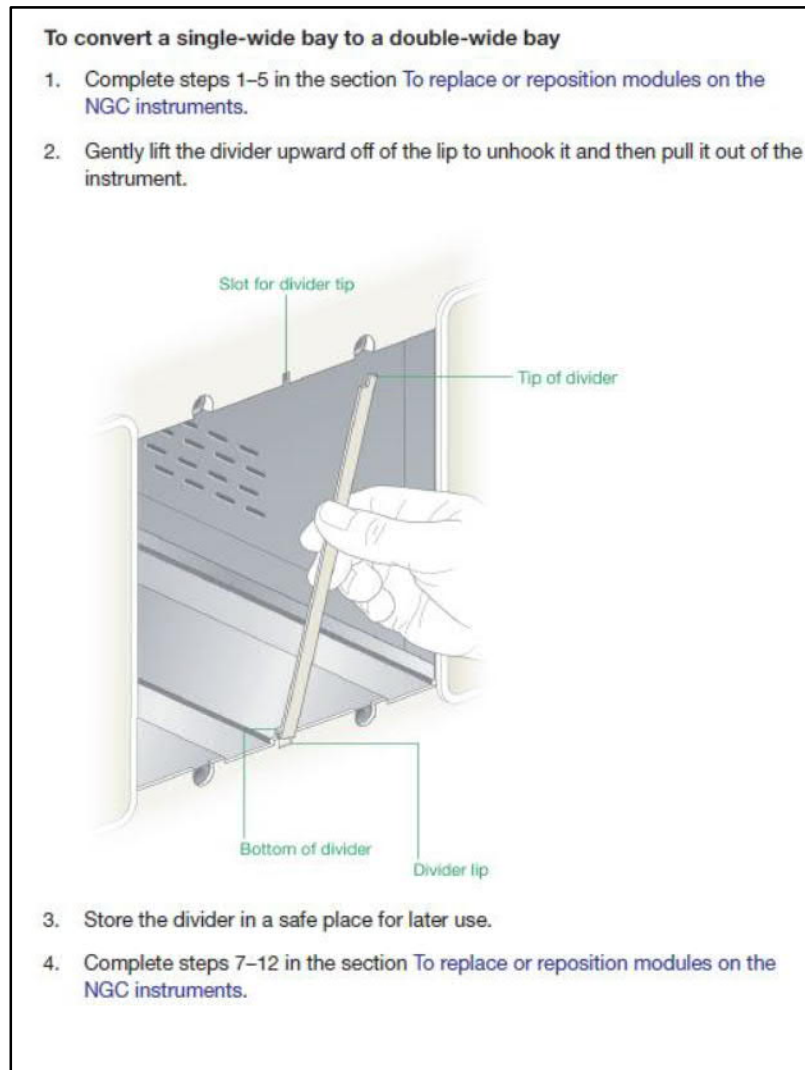
**Converting Bays to Fit Modules**

Some modules fit into single-wide bays while others require double-wide bays (such as the system and sample pump modules and the UV and UV/Vis detector modules). Bays can be converted from one size to the other by adding or removing the center divider.

The following image shows two adjacent, empty, single-wide bays.



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Ex. 5, pp. 236-238 (p. 236 not reproduced).

218. The pump modules and the UV detector modules are double-wide modules while the sample inject valve and pH valve are single-wide modules. This plainly demonstrates that these modules have a “standardized size and shape.” For example, just as Bio-Rad instructs in the Instrument Guide, an NGC user could, for

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example, remove a sample inject valve module and insert into the single-wide bay a pH valve module. Likewise, an NGC user could remove a pump module and insert into the double-wide bay a UV detector. Similarly, an NGC user could convert the double-wide bay into a single-wide bay and insert one or both of the sample inject valve module and/or the pH valve module into the two single-wide bays.

219. Finally, by having these standard sized bays, the NGC system “allows [for the modular fluid handling unit] to be exchanged with another component.” Bio-Rad’s Instrument Guide makes that clear, as it indicates that a person can replace or reposition modules:

**Replacing or Repositioning Modules on the NGC Instruments**

**WARNING!** Disconnect power to the NGC instrument before removing or repositioning any module. Do not attempt to service any component on the NGC instrument unless noted in this manual. Contact Bio-Rad for service requests.

**WARNING!** To reduce the chance of liquid seeping into the instrument, all open bays must be filled with the NGC Blank module (catalog #788-4005). The NGC instrument will not operate if it detects a slot without a module inserted.

**To replace or reposition modules on the NGC instruments**

1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. If necessary, disconnect all tubing lines to and from the module that you plan to replace or reposition.
3. Loosen the captive screws on the front of the installed module.
4. Firmly grasp both screws on the module and pull it forward out of its bay.

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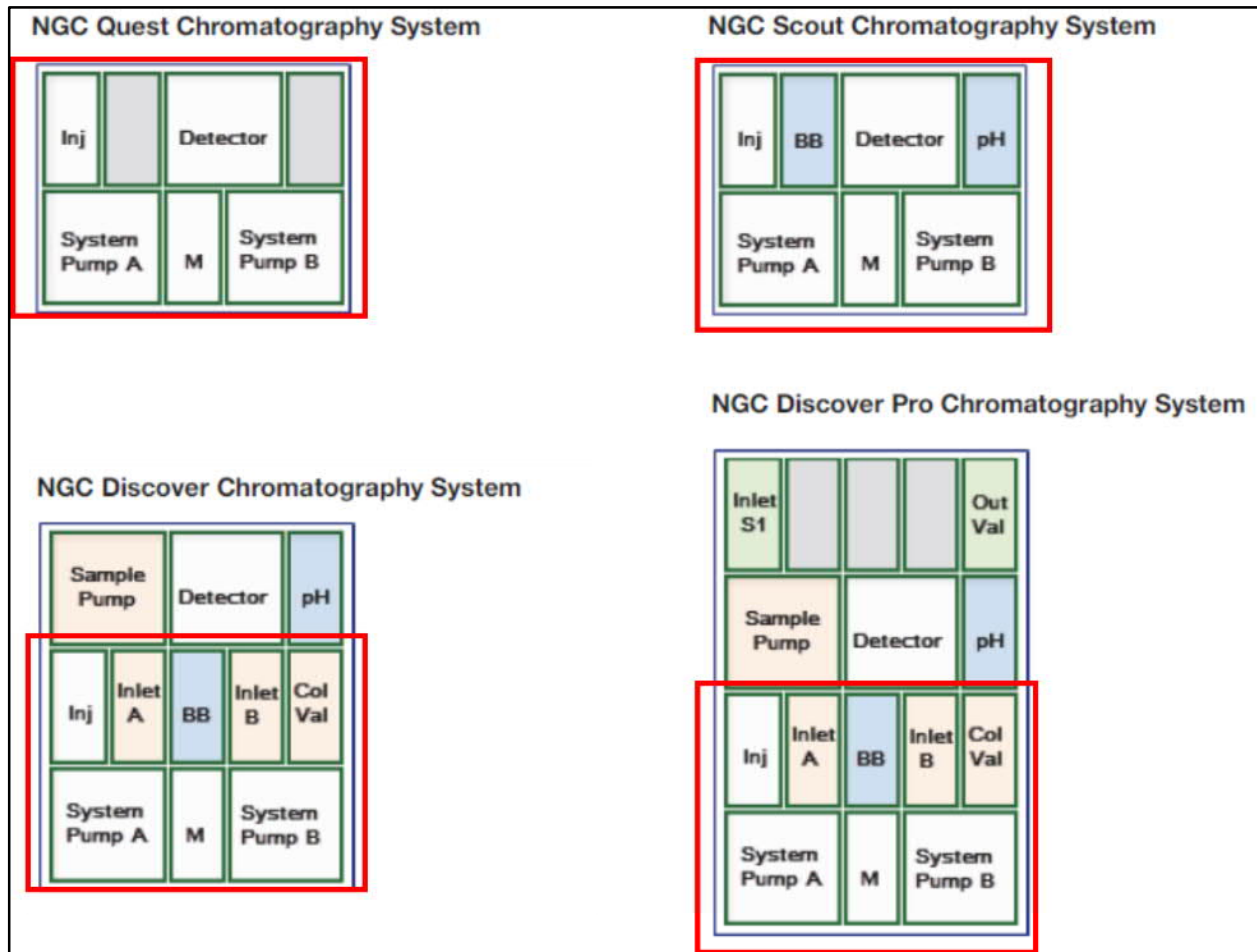
*See* Ex. 5, p. 233. *See also Id.* at 234-239.

220. Thus, this claim element is met by all NGC models.

- d. **“wherein the housing unit comprises on one external side of the housing unit a plurality of receiving positions, each receiving position adapted to receive the modular fluid handling units therein such that a fluid handling section thereof is on the external side of the housing unit, the receiving positions being arranged in a two dimensional array,**

221. One side of the housing unit used on all NGC models has “plurality of receiving positions.” Several drawings from Bio-Rad’s instrument guide are annotated below to show this:

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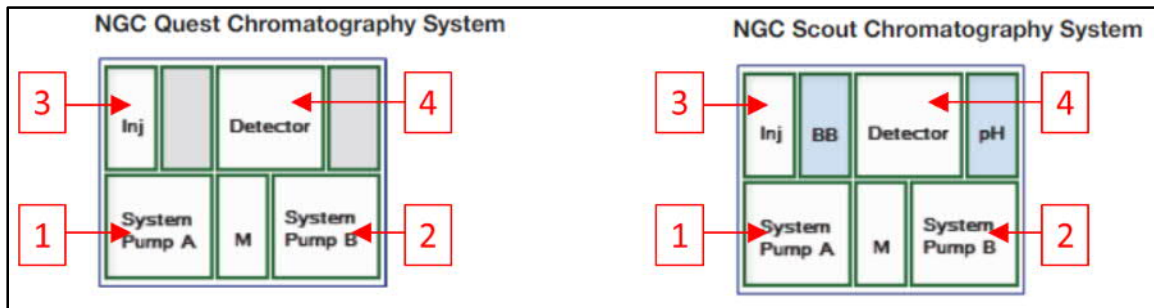


See Ex. 5, pp. 90-91. As can be seen in the above illustrations from Bio-Rad’s documentation, the NGC housing has multiple “receiving positions.” In the Quest and Scout models, no expansion housings are stacked on top of the main housing. Thus, the collection of receiving positions are boxed in red, as this will comprise the receiving positions of the “housing.”

222. The Quest and Scout housing can accommodate up to ten modules and thus can have up to ten “component receiving positions,” which satisfies the “at least

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four” requirement. As I discussed above, the size of Bio-Rad’s “bays” can be changed to be single-wide or double-wide bays, meaning depending on Bio-Rad’s customer choice, the Quest and Scout can accommodate as many as 10 modules (i.e., without using any double wide modules). In the Quest and Scout standard configurations, the following four positions in the below annotated version of figures from Bio-Rad’s Instrument Guide are “component receiving positions:”



See Ex. 5, p. 90.

223. These four receiving positions are plainly arranged in a two dimensional array, just as the claim requires.

224. Note the claim language only requires that the receiving positions be “adapted to receive said interchangeable modular components.” By reciting that the receiving positions are “adapted to receive,” the claim only requires that they be able to receive the interchangeable modular components.



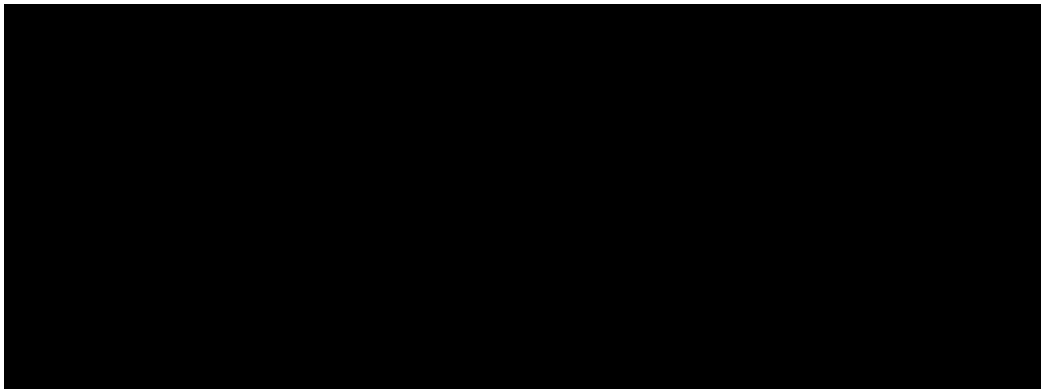
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225. As seen above, Bio-Rad's system pump modules, sample inject valve module, UV detector modules and pH valve modules are such that "fluid handling section thereof is on the external side of the housing unit." The "fluid handling section for these modules is as follows:

226. The specifications for each of the system pump, sample inject valve and UV Detector modules (and others) specify that they have a "fluid handling section" because they state that [REDACTED]

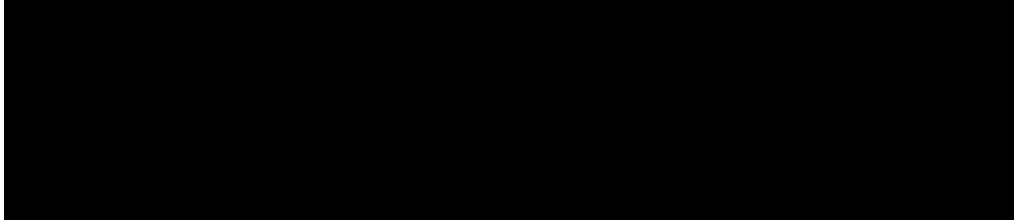


Ex. 13 (BRGE0096090) ([REDACTED] dule)

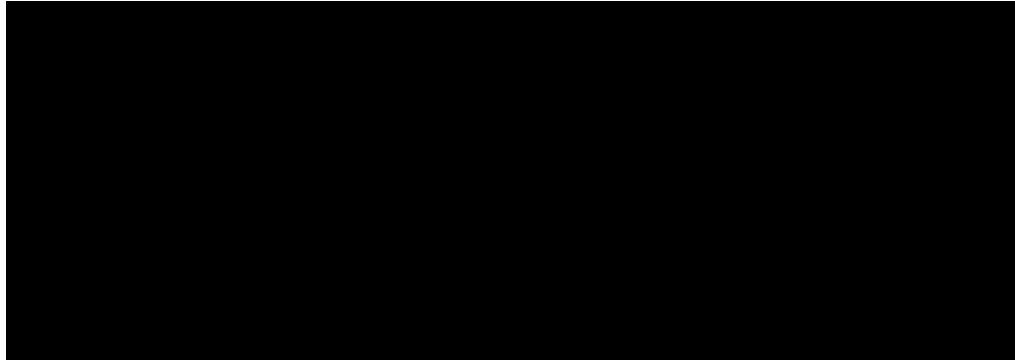


Ex. 14 (BRGEDEL000450753) [REDACTED]

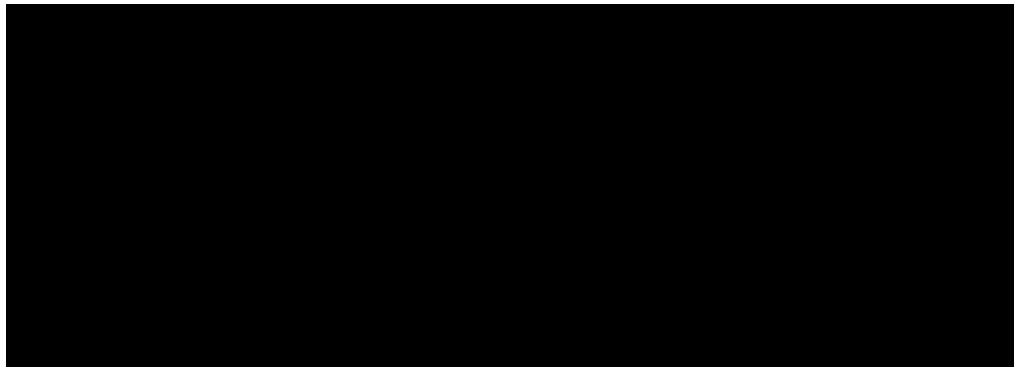
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Ex. 20 (BRGEDEL000281538) ( [REDACTED] )



Ex. 25 (BRGEDEL000451797) ( [REDACTED] )



Ex. 19 (BRGEDEL000282560) ( [REDACTED] ).

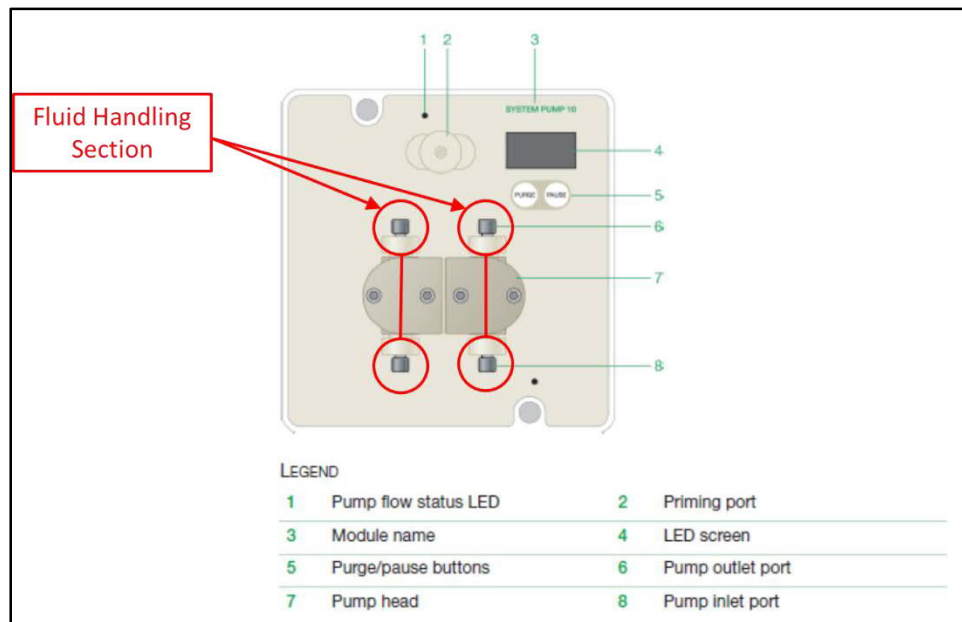
227. Mr. Chapman testified that these specifications were met for the pump modules (Chapman Tr. 529:12-530:17), sample inject valve module (Chapman Tr. 528:16-529:10), single wavelength detector module (Chapman Tr. 532:4-533:13), and the multi-wavelength UV detector (Chapman Tr. 533:15-534:17).

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228. These documents and Mr. Chapman's testimony demonstrates that the "fluidics section" for each of these modules, *e.g.*, the two system pump modules, the sample inject valve module, and the single wavelength detector module, the multi-wavelength UV detector module "include[] fluidics components," just as the Court's claim construction for "fluid handling section" requires.

229. Portions of the NGC Instrument Guide are annotated to show where the recited "fluid handling section" is found on these modules.

230. The fluid handling section for the system pump modules used in the NGC system is as follows:



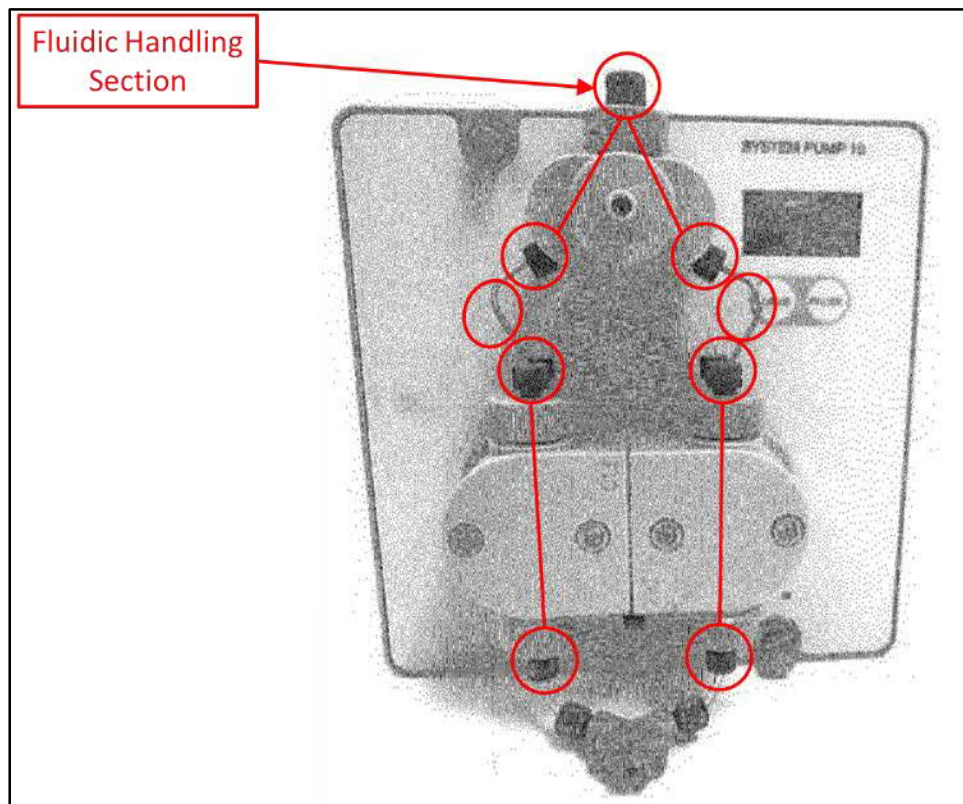
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Ex. 5, pp. 28-29. Note this figure is annotated to show hidden portions of the fluidics section, *i.e.*, a simplified illustration of the flow path within the fluidics section.

231. Note that the NGC Instrument Guide illustrates the F10 pump module, but the F100 pump module is essentially identical for purposes of this infringement analysis, meaning that the structure corresponding to the recited fluidics section is the same.

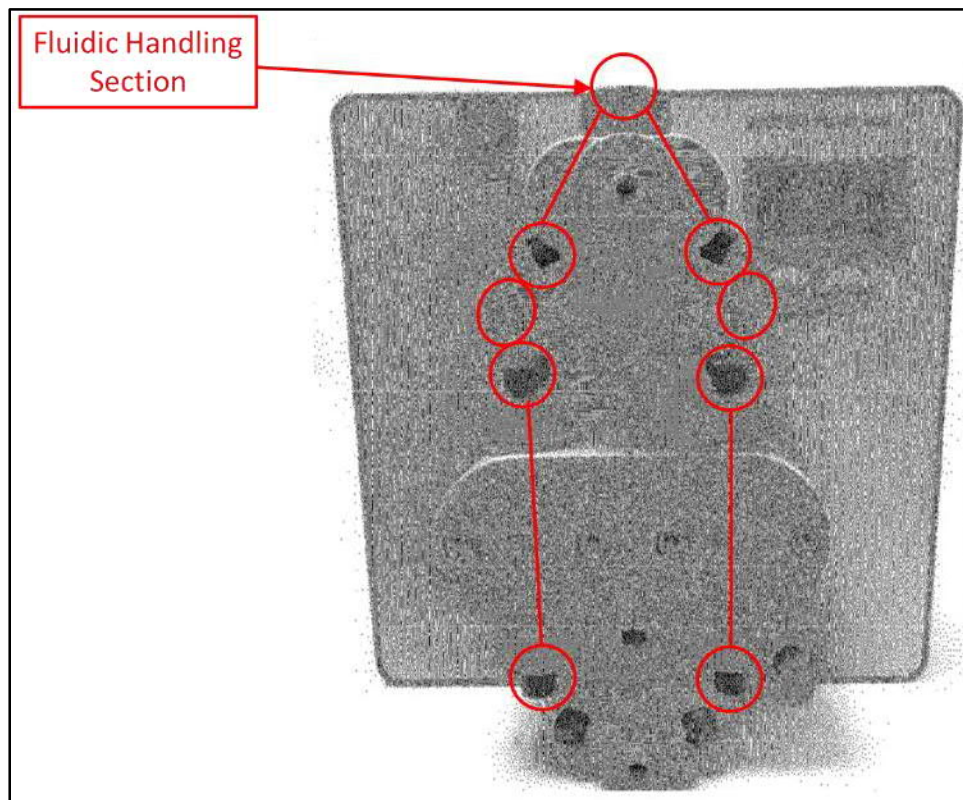
232. Note also that the section of the Instrument Guide does not illustrate the priming ports that can be on the system pump modules. These can be seen in the assembly drawings, which are annotated to show the fluidics section, as I did above, to show a simplified illustration of flow path within the fluidics section:

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Ex. 23 (BRGEDEL1507) (F10 pump module). *See also:*

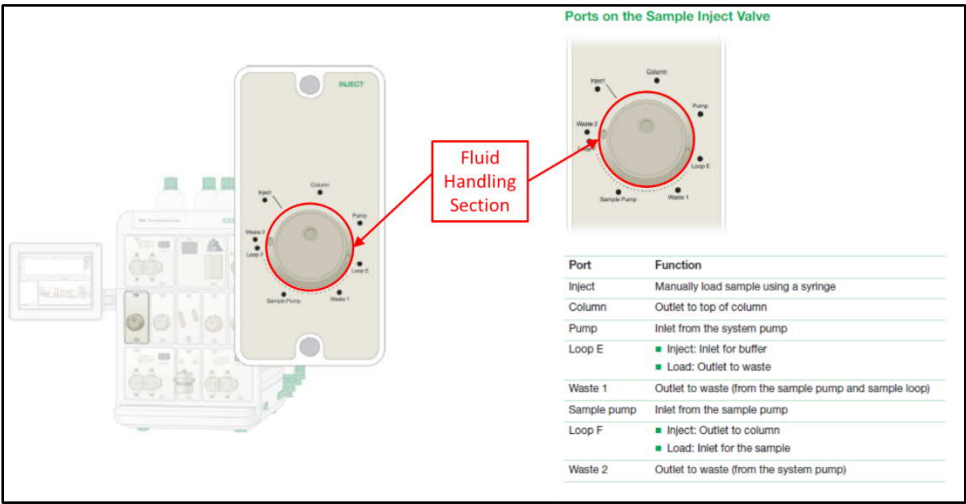
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Ex. 28, (BRGEDEL972) (F100 pump module)

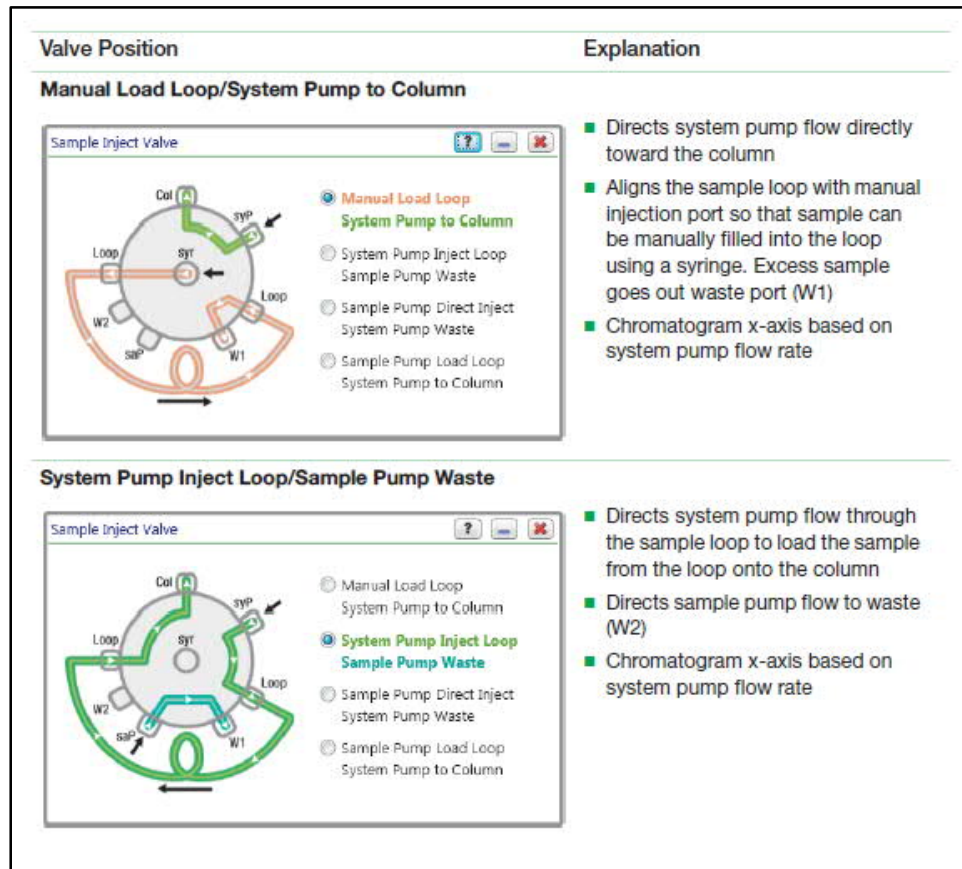
233. The fluid handling section for the sample inject valve module used in the NGC system is as follows:

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Ex. 5, pp. 37-38. This particular illustration does not show the complete fluid flow path, as the fluid flow paths of the fluidics section are not shown. However, this can be seen in, for example, the following figure from Bio-Rad’s Instrument Guide:

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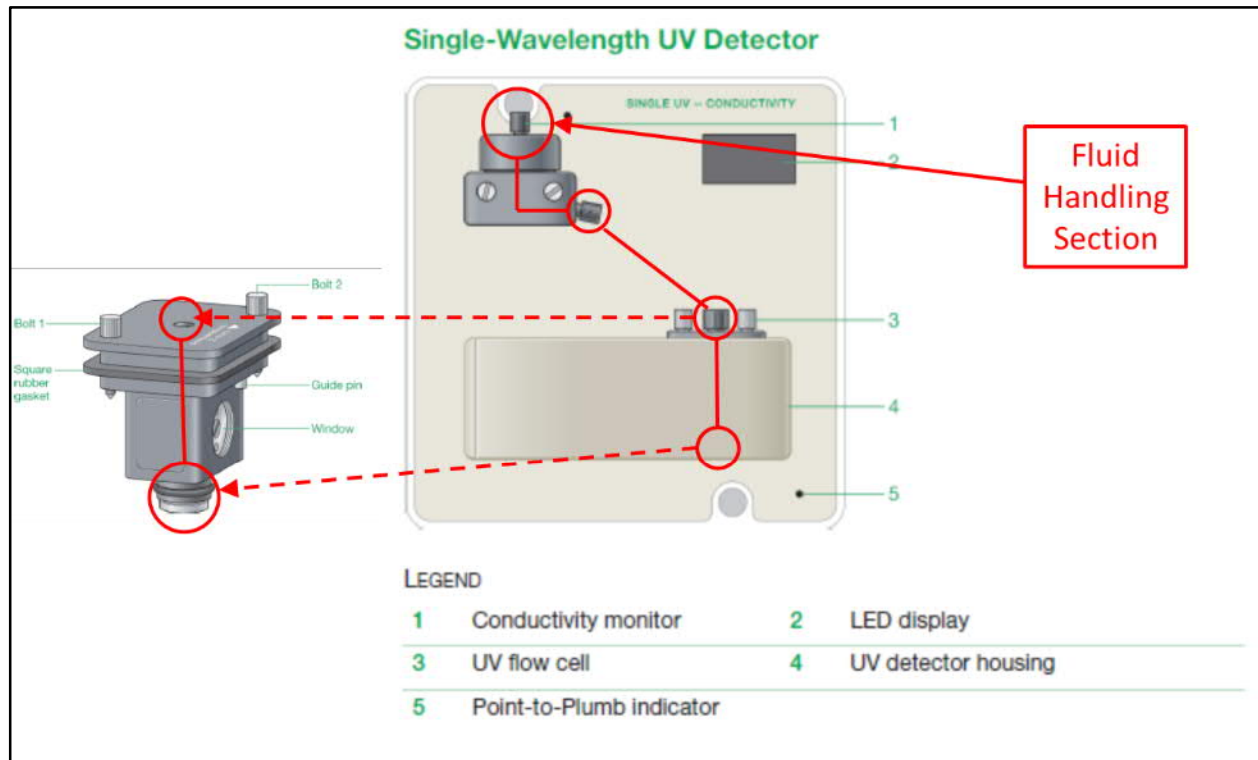


Ex. 5, p. 40.

234. The fluid handling section for the single wavelength UV detector module used in the NGC system is as follows:



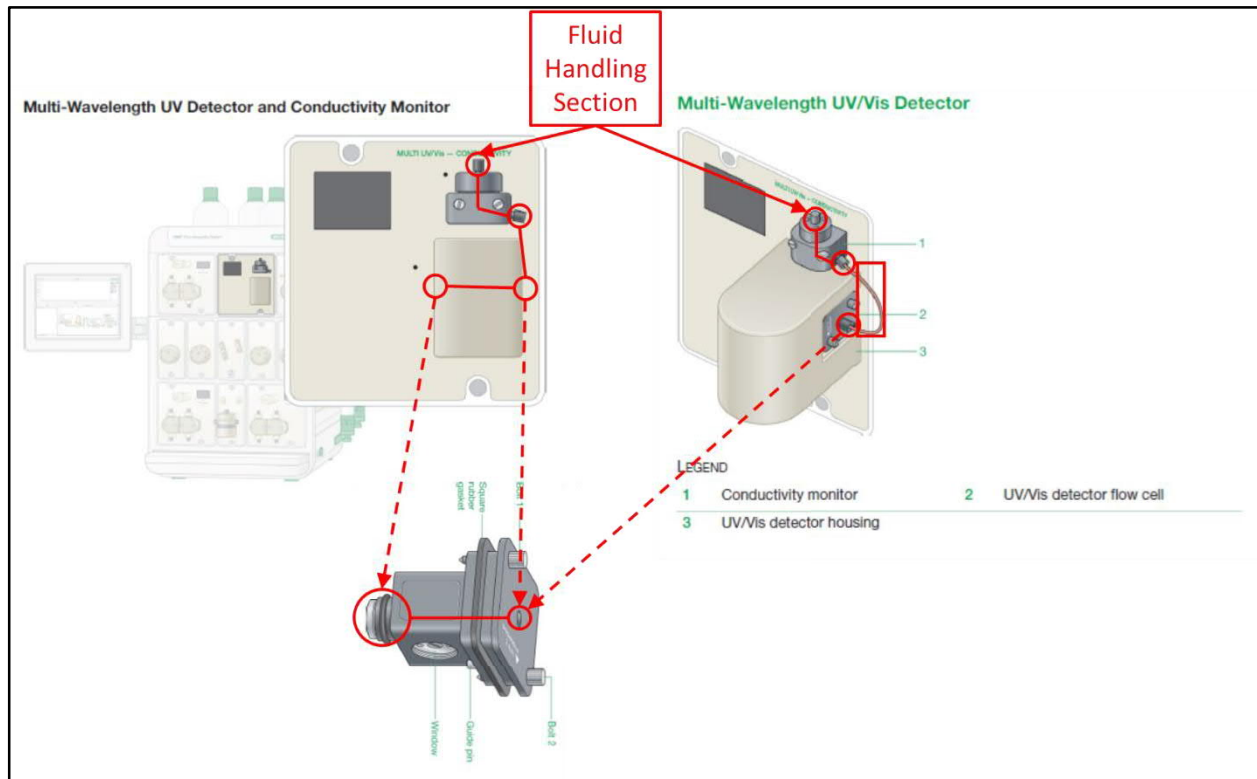
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Ex. 5, p. 67, 205.

235. The fluid handling section for the multi-wavelength UV detector module used in the NGC system is as follows:

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Ex. 5, p. 66, 69, 205.

236. As is seen, the fluid handling section of each of these modules include fluidic components like tubing inputs and outputs, valve components, pump components, flow cells, and other components through which fluid passes.

237. The Court's construction also requires that the fluid handling section *"not include non-fluidics components."* None of the fluidics portions I have identified above contain non-fluidics components. All they do is receive tubing inputs and outputs, and pass fluids through them. A POSITA would understand that these They are all plainly "fluidics components."

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238. Any non-fluidics components located externally are not a part of the claimed fluidics section. Indeed, as discussed, the Court explicitly stated at the claim construction hearing that there can be electronics external to the housing but not in the fluid handling section. Markman Tr. 97:16-25. Likewise, the Court also said each module can have more than just a fluid handling section and a non-fluidics section. *See e.g., id.*, at 100:14-23 and 103:8-13.

239. No non-fluidics components are in the fluid handling section I identify above.

240. In sum, each model of Bio-Rad's NGC system has an fluid handling section, just as claimed.

241. Thus, this claim element is plainly present in all models of the NGC system.

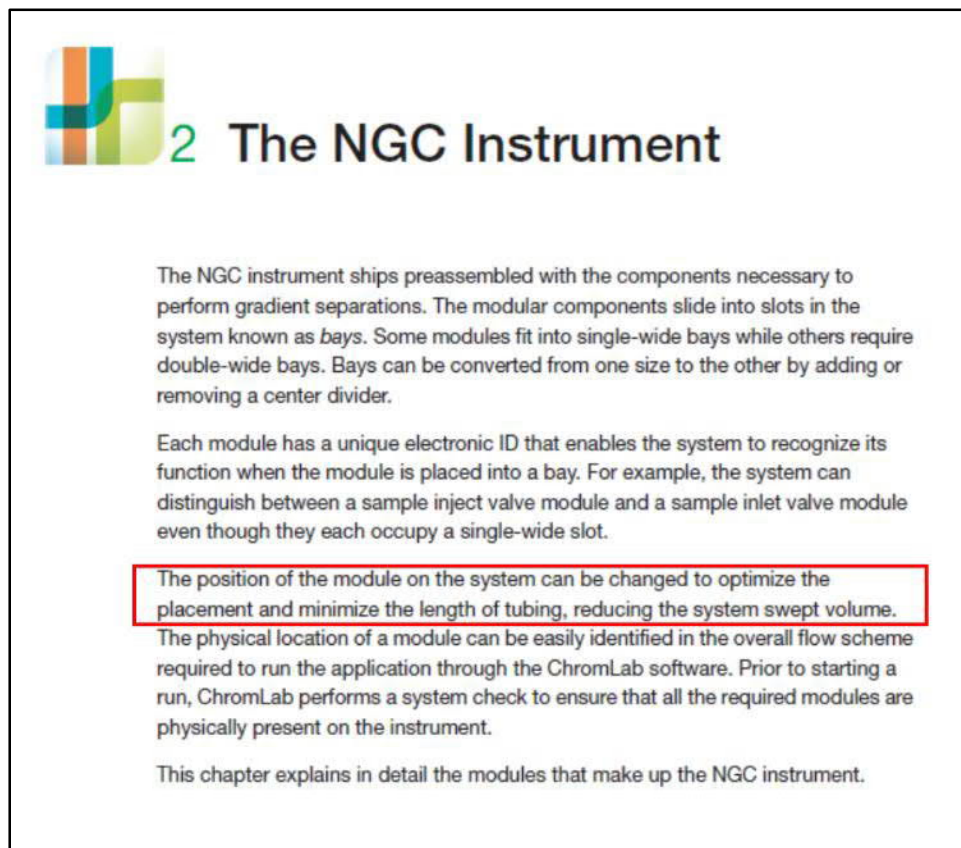
e. **“wherein each modular fluid handling unit is configured for insertion into the receiving positions of the housing unit”**

242. Each of the “modular fluid handling units” are “configured for insertion into the receiving positions of the housing unit.” *See* paragraphs 215-218.

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- f. **“wherein each modular fluid handling unit is ... is readily interchangeable amongst similarly sized and shaped receiving positions of the housing unit, such that positioning of the modular fluid handling unit with respect to other modular fluid handling units permits a fluid flow path to be readily modified, wherein the fluid flow path is formed by fluidic connections between the modular fluid handling units, and”**

243. The modular fluid handling units in all NGC models are “readily interchangeable amongst similarly sized and shaped receiving positions of the housing unit. Bio-Rad’s Instrument Guide establishes this:



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Ex. 5, p. 19.

244. Bio-Rad's Instrument Guide provides detailed instructions for how a person can easily move modules from a first bay to a second bay:

### Replacing or Repositioning Modules on the NGC Instruments

**WARNING!** Disconnect power to the NGC instrument before removing or repositioning any module. Do not attempt to service any component on the NGC instrument unless noted in this manual. Contact Bio-Rad for service requests.

**WARNING!** To reduce the chance of liquid seeping into the instrument, all open bays must be filled with the NGC Blank module (catalog #788-4005). The NGC instrument will not operate if it detects a slot without a module inserted.

**To replace or reposition modules on the NGC instruments**

1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. If necessary, disconnect all tubing lines to and from the module that you plan to replace or reposition.
3. Loosen the captive screws on the front of the installed module.
4. Firmly grasp both screws on the module and pull it forward out of its bay.

See Ex. 5, p. 233. See also *Id.* at 234-239. This process would be easy for a user of the NGC to perform, meaning that Bio-Rad's modules are "readily interchangeable." Note that the bays correspond to the recited "receiving positions."

245. Likewise, as I have discussed, Bio-Rad's NGC has modules of two sizes, and they fit in correspondingly sized bays (single-wide or double-wide):

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246. In the section of the Instrument Guide entitled “Replacing or Repositioning Modules on the NGC Instruments,” Bio-Rad shows the following:



Ex. 5, p. 234. The NGC can accommodate modules that are “single-wide” and “double-wide.” This is shown below:

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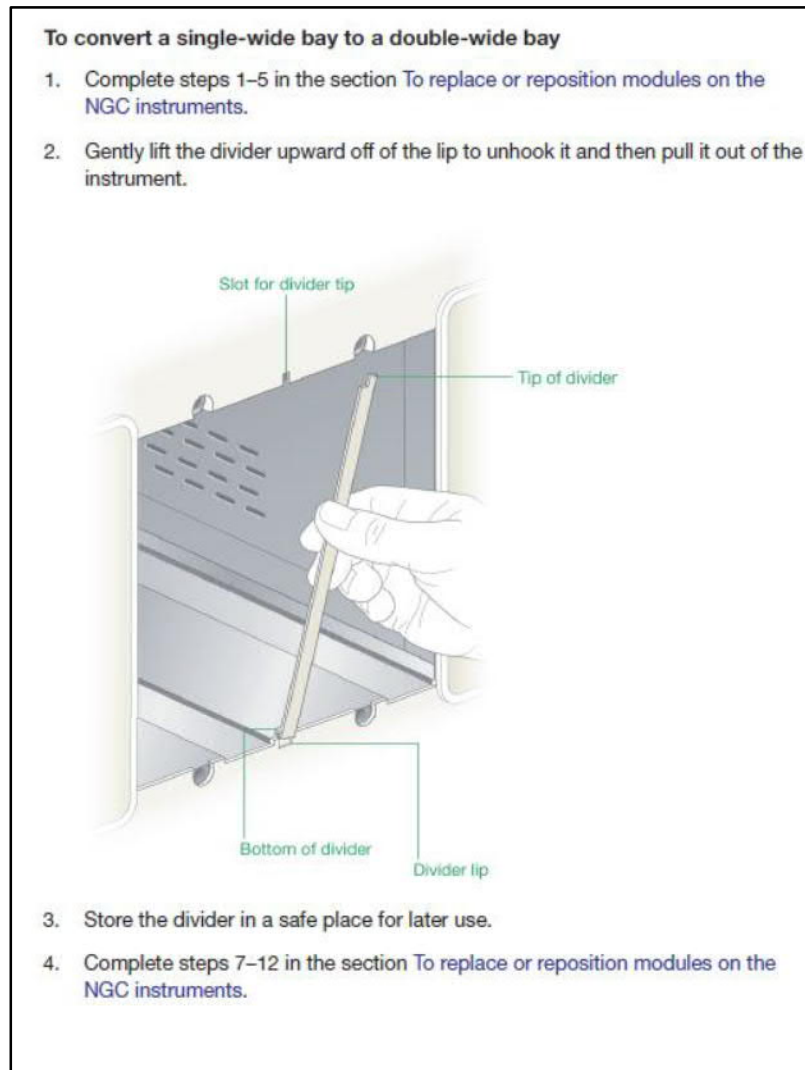
**Converting Bays to Fit Modules**

Some modules fit into single-wide bays while others require double-wide bays (such as the system and sample pump modules and the UV and UV/Vis detector modules). Bays can be converted from one size to the other by adding or removing the center divider.

The following image shows two adjacent, empty, single-wide bays.



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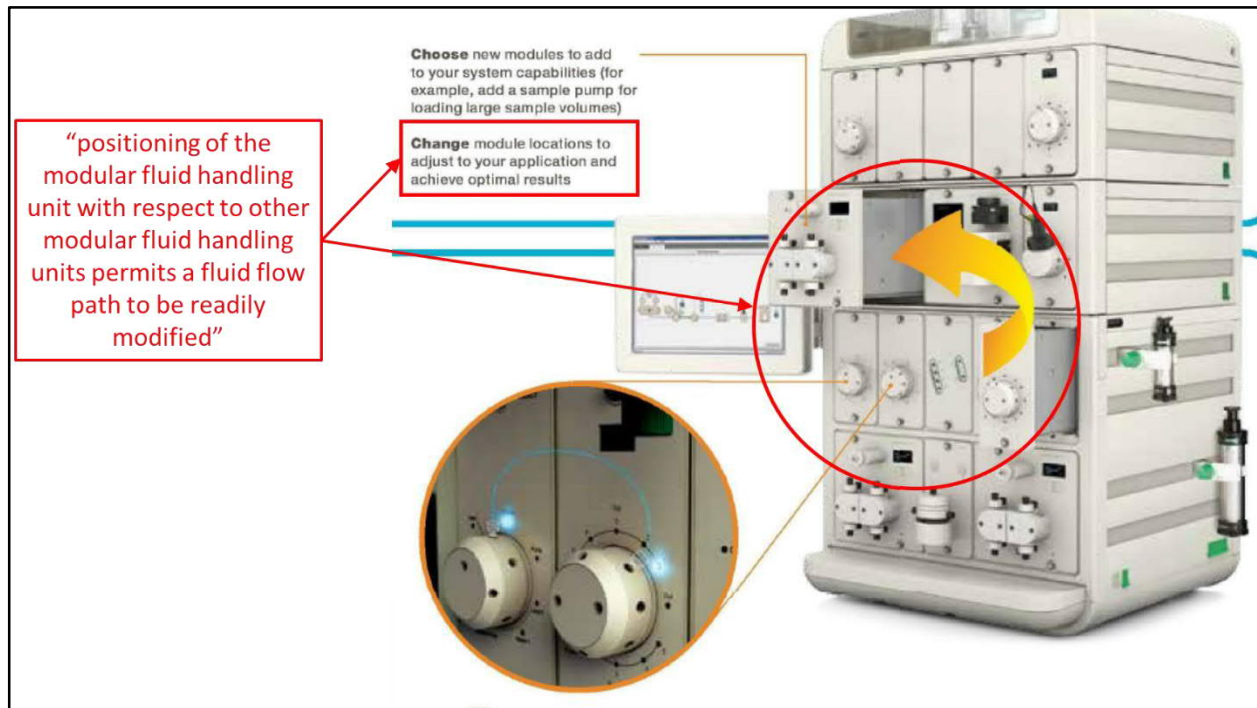


Ex. 5, pp. 236-238 (p. 236 not reproduced).

247. In addition, “positioning of the modular fluid handling unit with respect to other modular fluid handling units permits a fluid flow path to be readily modified,” just as claimed. See Ex. 5, p. 19, excerpted above. See also:



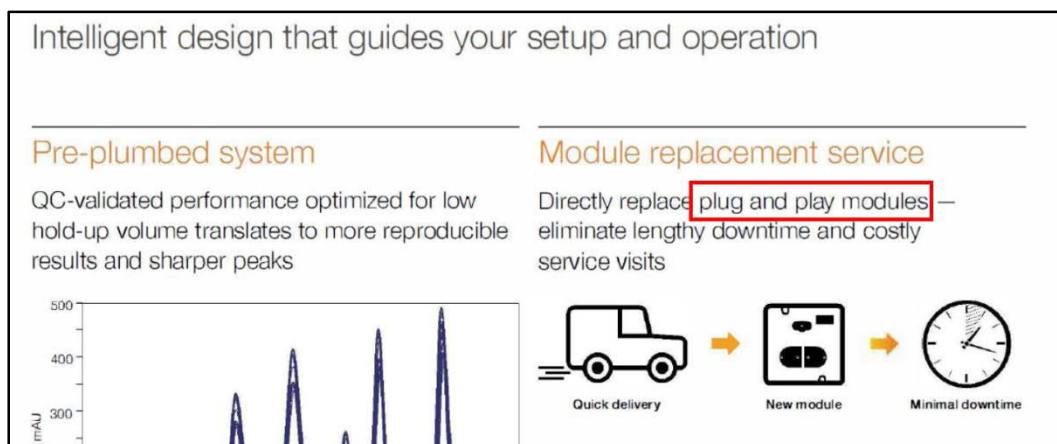
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*NGC Chromatography Systems - Comprehensive Solutions For Protein Purification*

(Ex. 21 (BRGEDEL293539). This same document refers to Bio-Rad's modules as

"plug and play:"



Ex. 21, p. BRGEDEL293542.

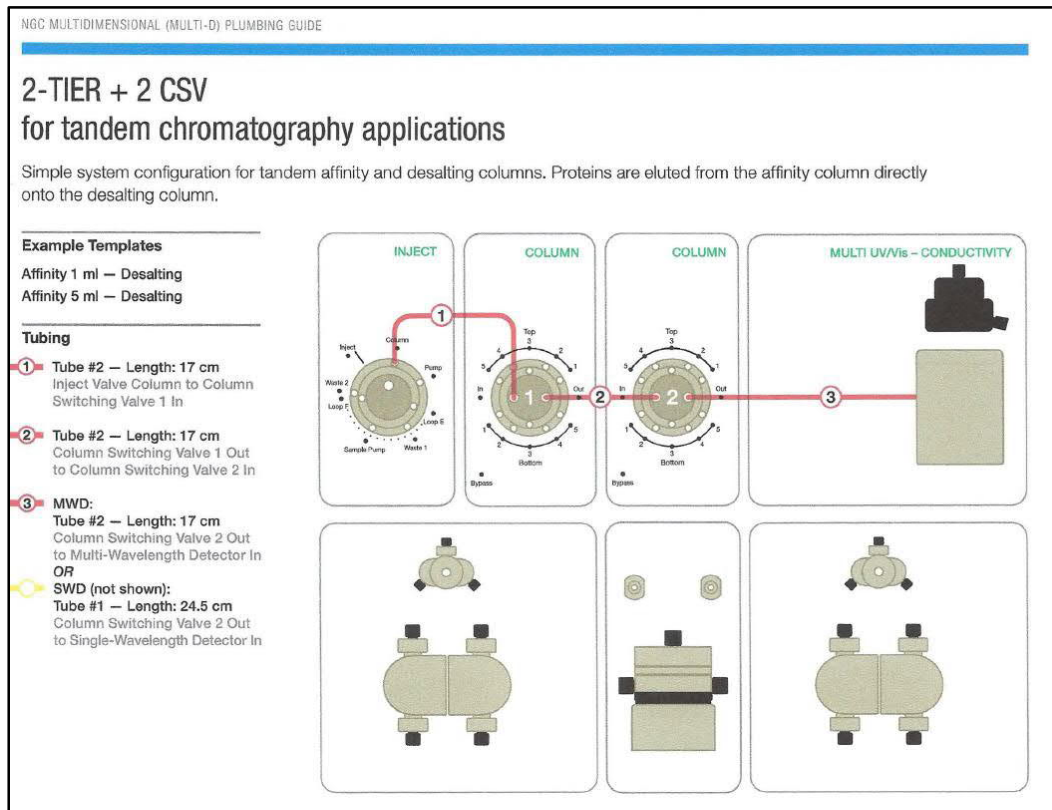
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248. Also, Exhibit 22, entitled *NGC Chromatography Systems - Multidimensional (Multi-D) Plumbing Guide*, further indicates that modules can be placed in different receiving positions:

This guide is designed to help plumb your NGC System for multidimensional (Multi-D) chromatography applications. These techniques can help enhance sample recovery and improve productivity by minimizing the steps and time required for protein purification. In addition, it shows the optimal locations for module placement to minimize tubing length and swept volume.

Ex. 22, p. 2. Indeed, the setup on p. 2, for “2-tier + 2 CSV for tandem chromatography applications,” shows a module arrangement that differs from the standard Quest and Scout configurations:

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Ex. 22, p. 3.

249. Further, as discussed, Mr. Bland testified that this feature was present:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

Bland Tr. 100:8-101:1.

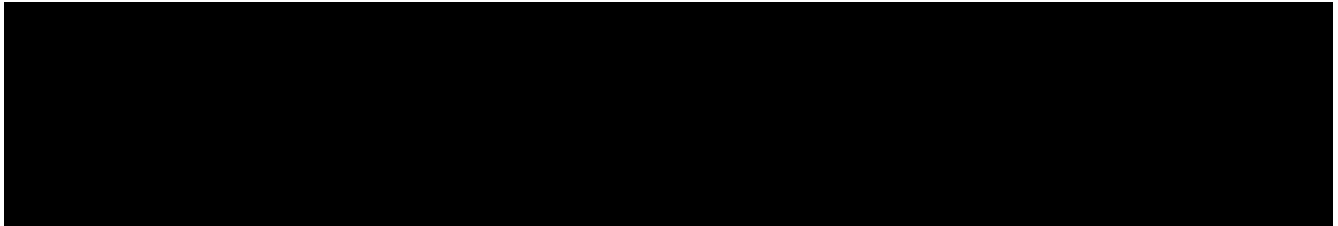
250. Finally, all Bio-Rad NGC models form a fluid flow path “by fluidic connections between the modular fluid handling units.” As discussed, the fluid handling section of the modules I identified have tubing inputs and outputs. Tubing is connected between such inputs and outputs to create a “fluid flow path,” just as claimed.

251. In sum, all NGC models fall within the scope of this claim element.

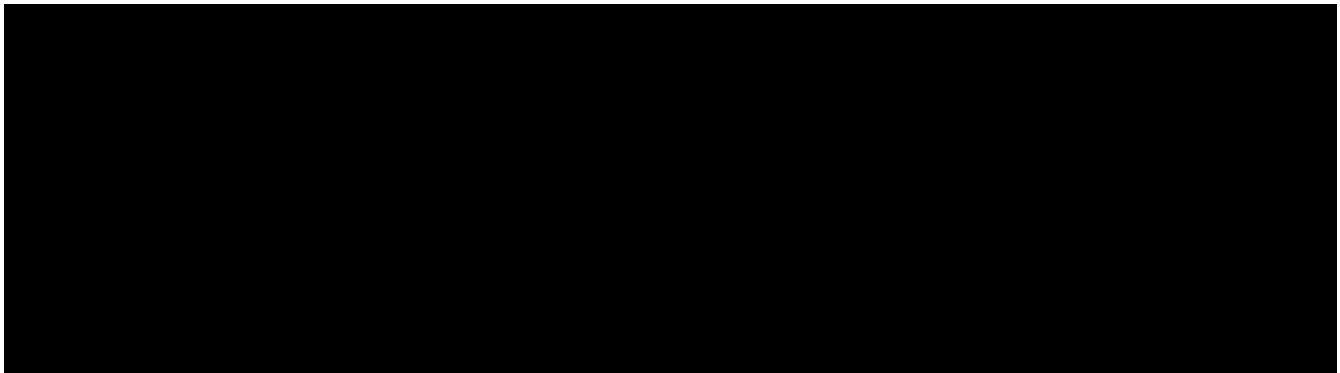
- g. “wherein each modular fluid handling unit ... includes a CPU for independently performing fluid control operations in response to instructions over a system BUS.”**

252. Each of the “at least modular fluid handling units” I identified above has a “CPU.” As noted above, the parties agreed that CPU should be construed as “central processing unit,” which is what the abbreviation “CPU” stands for. The specifications for each demonstrate the presence of a CPU on each module required by the claim:

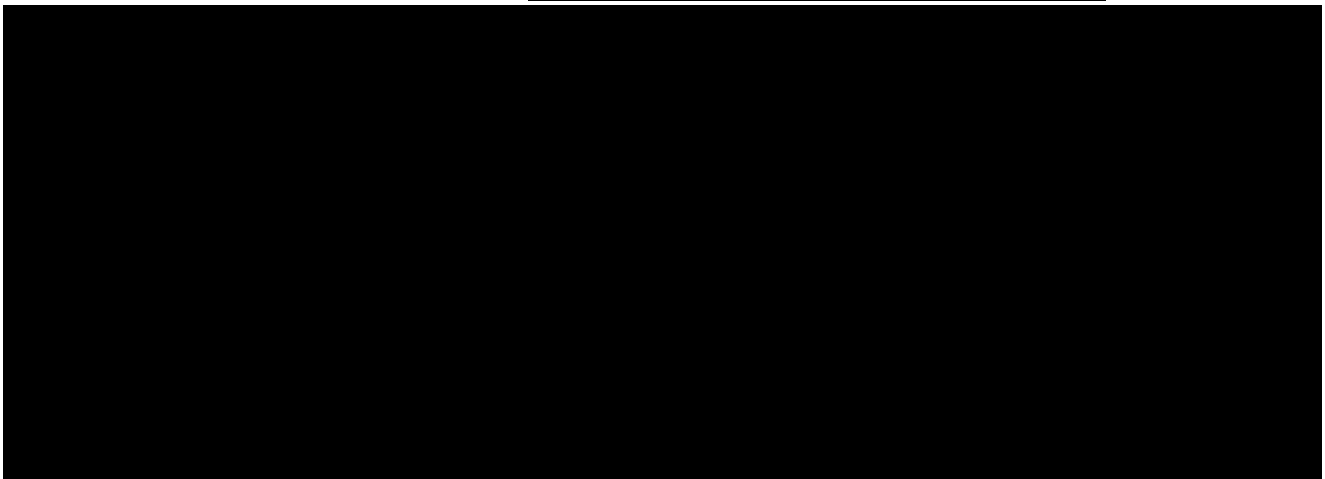
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Ex. 14 (BRGEDEL000450746) ( [REDACTED] )



Ex. 20 (BRGEDEL000281532) ( [REDACTED] )



Ex. 13 (BRGE0096081) ( [REDACTED] )

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[REDACTED]

Ex. 19 (BRGEDEL000282542) [REDACTED]

253. As can be seen from the above excerpts, each of these Bio-Rad module specifications states: [REDACTED]

[REDACTED]

254. First, it is well known that microcontrollers include CPUs. Mr. Bland testified that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

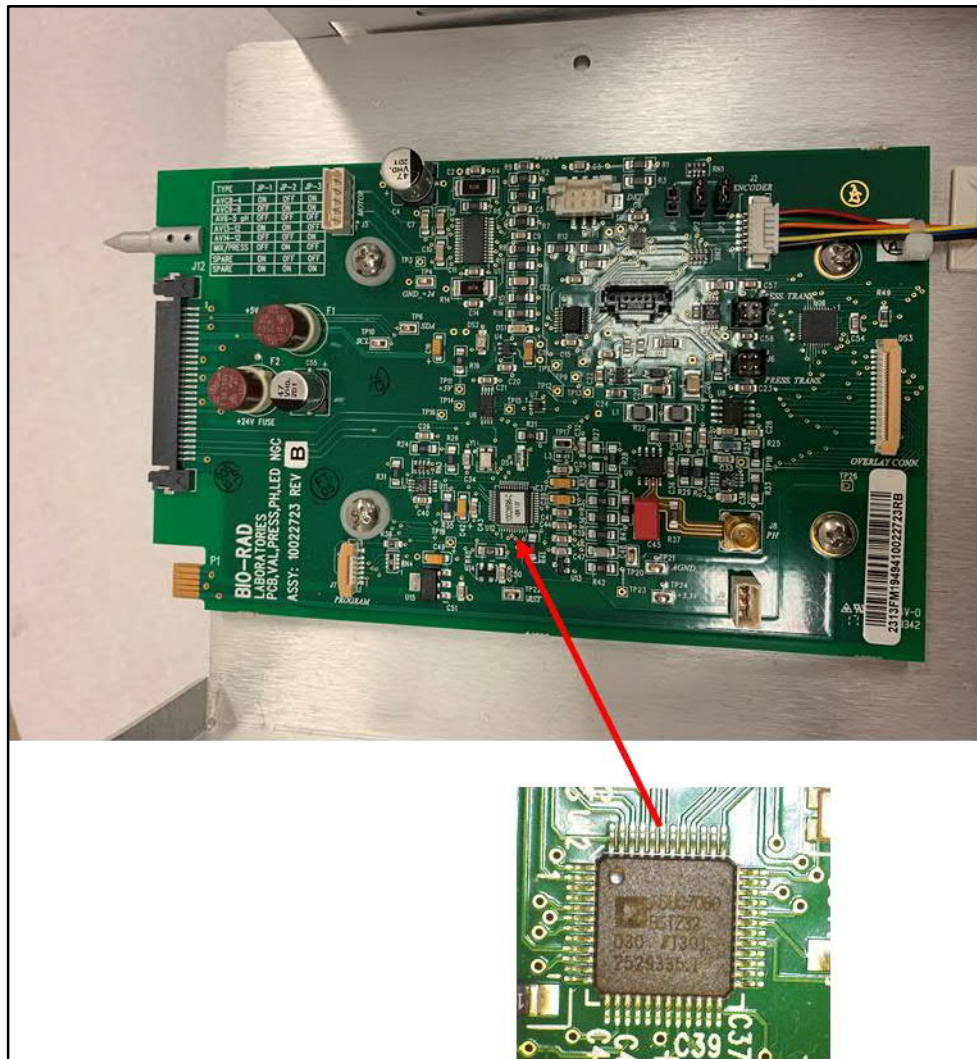
[REDACTED]

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Bland Tr. 105:2-105:17.

255. Cytiva photographed the circuit board inside one of the modules of the NGC it has, which confirms that each module has a CPU:

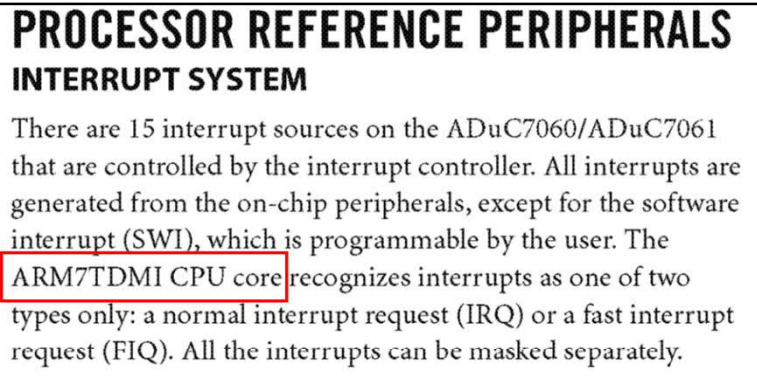




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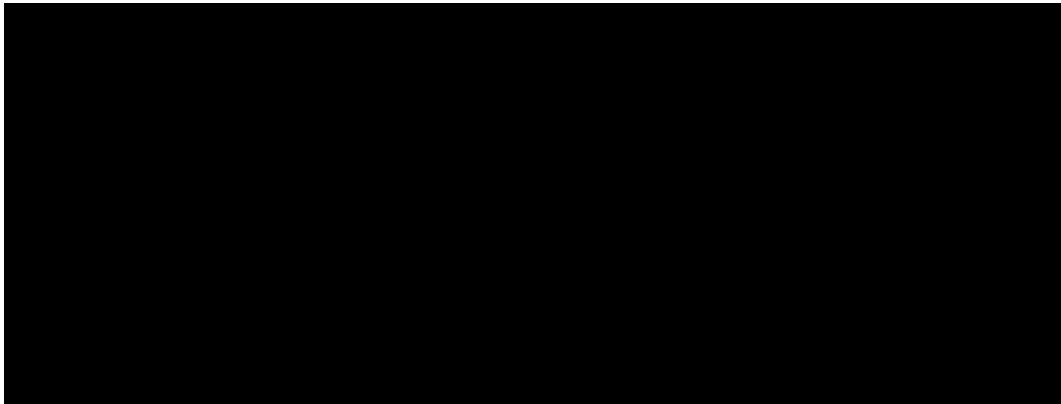
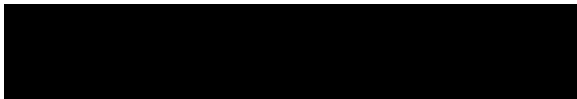
256. In the photo, you can see the markings for this part is for an ADC7060.

The datasheet for this component confirms that it has a CPU:



Ex. 18 (GEHCDEL129737, at GEHCDEL129796).

257. Bio-Rad's internal firmware specifications further demonstrate that the



Ex. 17 (BRGEDEL98274).

258. The portions of specifications I excerpted above also demonstrate that the integral microcontroller on each module allows ■the interchangeable modular



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component to independently perform operations in response to instructions over the system bus.” As discussed, the Bio-Rad specifications each state that [REDACTED]

[REDACTED] This demonstrates that the CPU on each module “performs operations” since Bio-Rad’s documents unambiguously state that [REDACTED]

259. The claim language further requires that the CPUs “allow[] the interchangeable modular component to independently perform operations in response to instructions over the system bus.” This plainly happens. First, the language “independently perform operations” refers to the modules themselves, and thus requires that the particular module’s operations be independent from the operations of other modules installed in the system. This is further supported by the claim language reciting that the independent operations be performed “in response to instructions over the system bus.” A POSITA would understand this means that the CPU operates in conjunction with other processing devices in the system, and plainly does not mean that the in-module CPUs must operate completely by themselves. Such a reading of the claim would ignore the claim language and defy common engineering principles. Indeed, the fact that the specification describes use

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of a “master” control unit plainly would indicate to a POSITA that other processing devices are involved.

260. At his deposition, Mr. Iovanni testified regarding the meaning of the word “independently” when questioned regarding Exhibit 4:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Iovanni Tr. 105:9-105:22. Mr. Bland testified that [REDACTED]

[REDACTED] (in the context of Exhibit

47, the system pump specification):

[REDACTED]

[REDACTED]

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[illegible]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Bland Tr. 105:18-108:13. When questioned regarding the column switch valve module (Exhibit 50), Mr. Bland further testified that [REDACTED]

[REDACTED]

[REDACTED]

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[illegible]

Bland Tr. 129:2-130:16.

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261. In addition, I have reviewed the declaration provided by Nenad Vukicevic, who reviewed portions of Bio-Rad's source code for the NGC system, and this confirms the documentation and testimony that Bio-Rad's modular fluid handling units independently perform operations "in response to instructions over the system bus." See e.g., Paragraphs 5-8, 10.

262. In sum, this claim element is present in all models of the NGC system.

263. Thus, all Bio-Rad NGC models infringe this claim.

**C. '591 Patent**

**1. Claim 9**

264. Claim 9 depends on claim 1. Thus, I first analyze claim 1. I note that claim 1 of the '591 patent is almost identical to claim 1 of the '420 patent. The only differences are demonstrated in this redline:

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**a.**

1. An automated liquid chromatography system comprising: a housing; a master control unit connected to a system bus; and ~~three~~two or more fluid handling units arranged as interchangeable modular components comprising (i) an external fluidics section, (ii) an internal non-fluidics section including a bus connector for directly connecting the interchangeable modular component with the system bus, and (iii) a panel member arranged to separate the fluidics section from the non-fluidics section; wherein the housing comprises a liquid handling panel with ~~at least four~~two ~~or more~~ component receiving positions ~~arranged in a two dimensional array and~~ adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing; wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus; wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus; wherein the master control unit is arranged to automatically identify interchangeable modular components; wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least ~~three~~two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components; and wherein the system is capable of performing automated liquid chromatography.

265. As can be seen, the difference between these two claims is that claim 1 of the '591 patent requires only two (as opposed to three) fluid handling units arranged as interchangeable modular components, and these two need not be arranged in a two dimensional array. For completeness, I address this claim here.

**(i) An automated liquid chromatography system comprising:**

266. See Section VIII.A.1.a.

**(ii) a housing;**

267. See Section VIII.A.1.b.

**(iii) a master control unit connected to a system bus;  
and**

268. See Section VIII.A.1.c.

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- (iv) two or more fluid handling units arranged as interchangeable modular components comprising**

269. See Section VIII.A.1.d. Note that this claim element is broader than that in the similar claim from the '420 patent, the difference being the number of interchangeable modular components. The infringement analysis is thus the same.

- (v) (i) an external fluidics section,**

270. See Section VIII.A.1.e.

- (vi) (ii) an internal non-fluidics section**

271. See Section VIII.A.1.f.

- (vii) including a bus connector for directly connecting the interchangeable modular component with the system bus, and**

272. See Section VIII.A.1.g.

- (viii) (iii) a panel member arranged to separate the fluidics section from the non-fluidics section,**

273. See Section VIII.A.1.h.

- (ix) wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing,**

274. See Section VIII.A.1.i. Note this claim element, unlike the corresponding element in claim 1 of the '420 patent, does not require that the two component receiving positions be arranged in a two dimensional array. Because this



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element is thus broader, the infringement analysis is essentially the same, except there is no need to show this particular limitation.

- (x) **wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus,**

275. See Section VIII.A.1.j.

- (xi) **wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus,**

276. See Section VIII.A.1.k.

- (xii) **wherein the master control unit is arranged to automatically identify interchangeable modular components,**

277. See Section VIII.A.1.l.

- (xiii) **wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components, and**

278. See Section VIII.A.1.m.

- (xiv) **wherein the system is capable of performing automated liquid chromatography.**

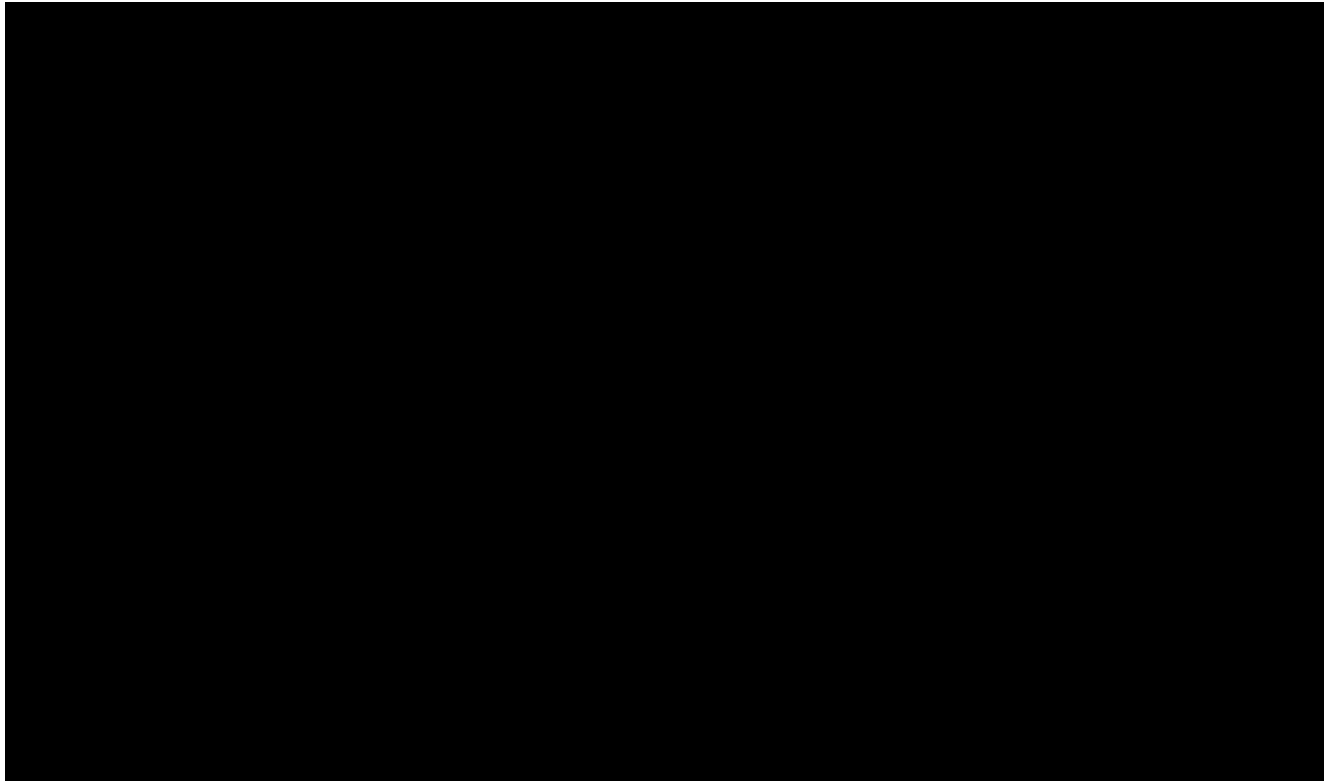
279. See Section VIII.A.1.n.

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**b. Claim 9**

280. Claim 9 requires that “the system include[] at least two fluid pumps.”

Each of Bio-Rad’s NGC models comes standard with two system pumps:



See BRGEDEL000070409. As seen, all NGC models come standard with either two F10 pump modules or two F100 modules. Thus, this claim is infringed.

**2. Claim 14**

281. Claim 14 depends on claim 13, which in turn depends on claim 1. Thus, to demonstrate Bio-Rad’s infringement of claim 14, I first demonstrate how claim 13 is infringed.

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**a. Claim 13**

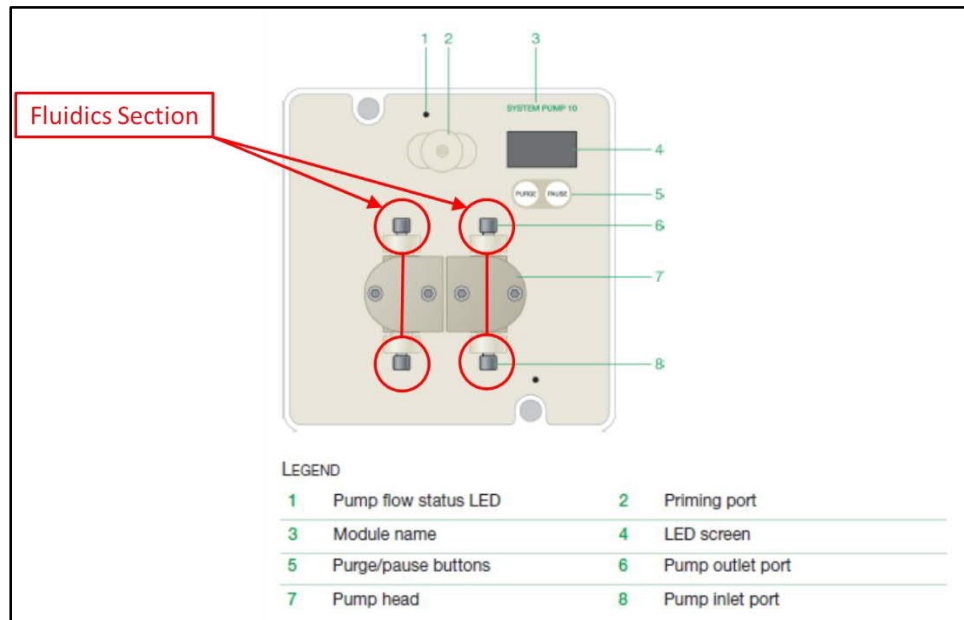
282. Claim 13 requires that the “fluidics section” of each of the two interchangeable modular component” recited in claim 1 have “one or more fluid connectors for connecting the fluid handling unit to a liquid chromatography fluid path and wherein all fluid connectors are on a wet side of the panel member.”

283. Each NGC model has this feature. Note that the “wet side” of the panel member is the external portion.

284. As seen in Section VIII.A.1.e the “fluidics section of each interchangeable modular component comprises one or more fluid connectors for connecting the fluid handling unit to a liquid chromatography fluid path. For convenience, I reproduce the annotated drawings I placed in that Section, where it can plainly be seen that the “fluidics section” comprises “one or mor fluid connectors ...”

285. System pump modules:

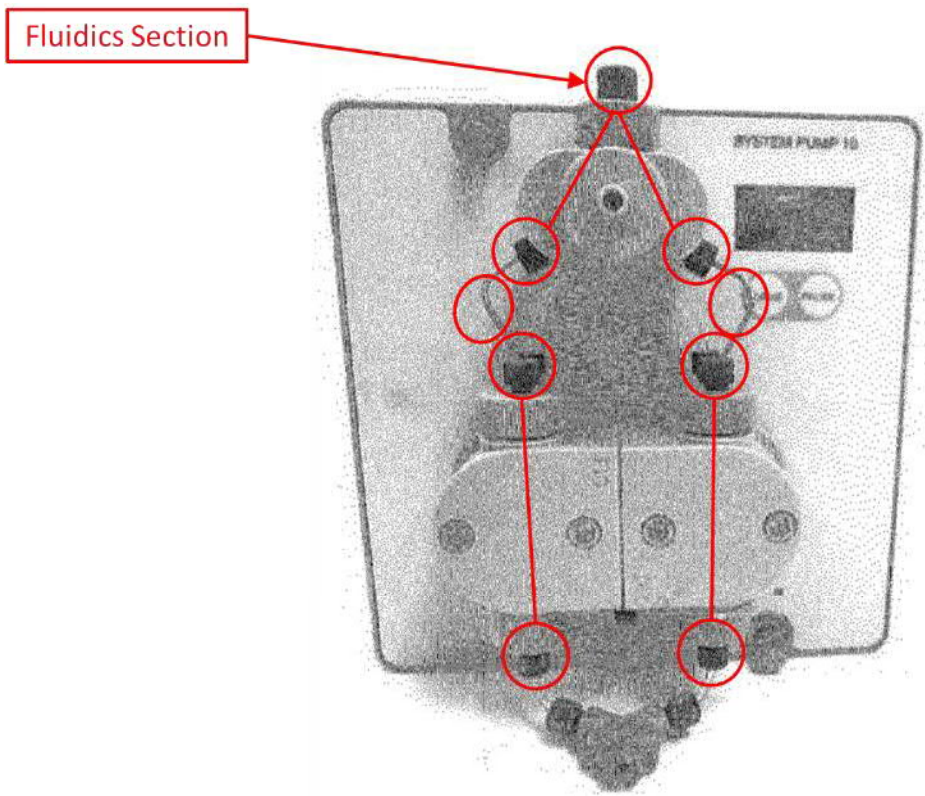
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Ex. 5, pp. 28-29. As discussed, Bio-Rad's F100 pump module will look the same and have the same fluidics section.

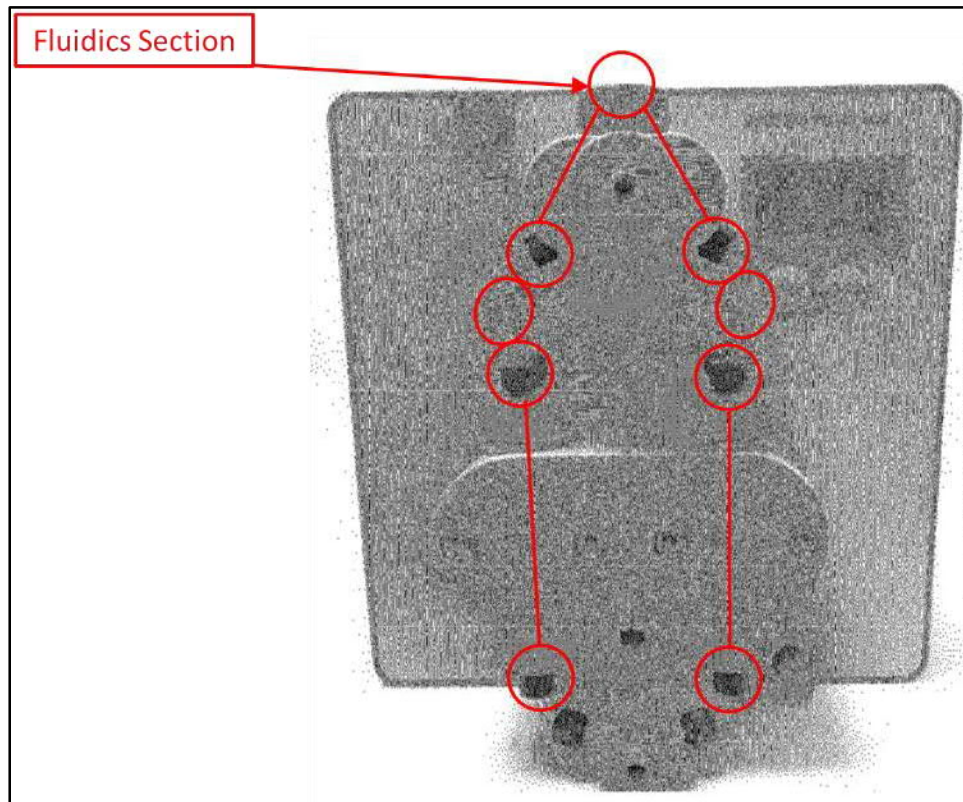
286. Below is another view of Bio-Rad's system pump module, this time showing the priming port:

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Ex. 23 (BRGEDEL1507) (F10 pump module). *See also:*

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Ex. 28, (BRGEDEL972) (F100 pump module)

287. This claim element further requires that all the recited fluid connectors be “on an external side of the panel member.” The above illustrations of Bio-Rad’s modules demonstrates that this is the case.

288. Thus, this claim element is present in all Bio-Rad NGC models.

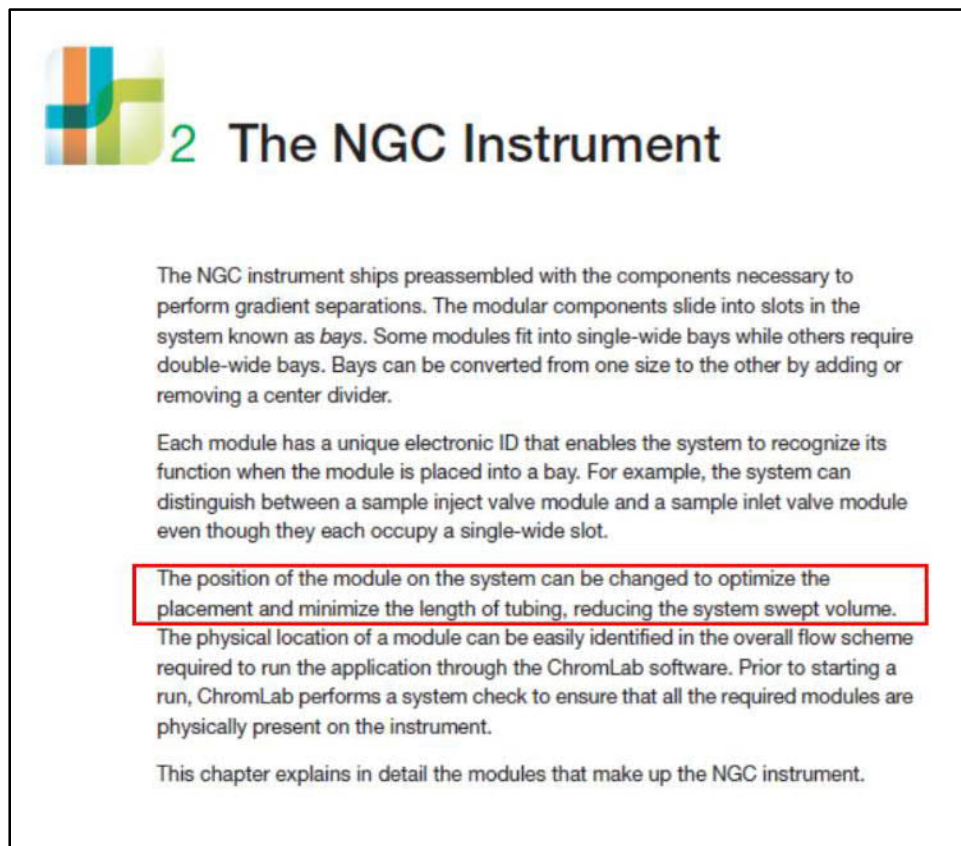
**b. Claim 14**

289. Claim 14 requires that “the liquid chromatography fluid path [of the system recited in claim 13] is reconfigurable by moving the interchangeable modular

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components freely between the component receiving positions.” This is present in all NGC models.

290. The “liquid chromatography fluid path” in each of Bio-Rad’s NGC models is reconfigurable “by moving the interchangeable modular components freely between the component receiving positions.” Bio-Rad’s Instrument Guide explicitly says this functionality is possible:



Ex. 5, p. 19.



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291. Bio-Rad's Instrument Guide provides detailed instructions for how a person can easily move modules from a first bay to a second bay:

**Replacing or Repositioning Modules on the NGC Instruments**

**WARNING!** Disconnect power to the NGC instrument before removing or repositioning any module. Do not attempt to service any component on the NGC instrument unless noted in this manual. Contact Bio-Rad for service requests.

**WARNING!** To reduce the chance of liquid seeping into the instrument, all open bays must be filled with the NGC Blank module (catalog #788-4005). The NGC instrument will not operate if it detects a slot without a module inserted.

**To replace or reposition modules on the NGC instruments**

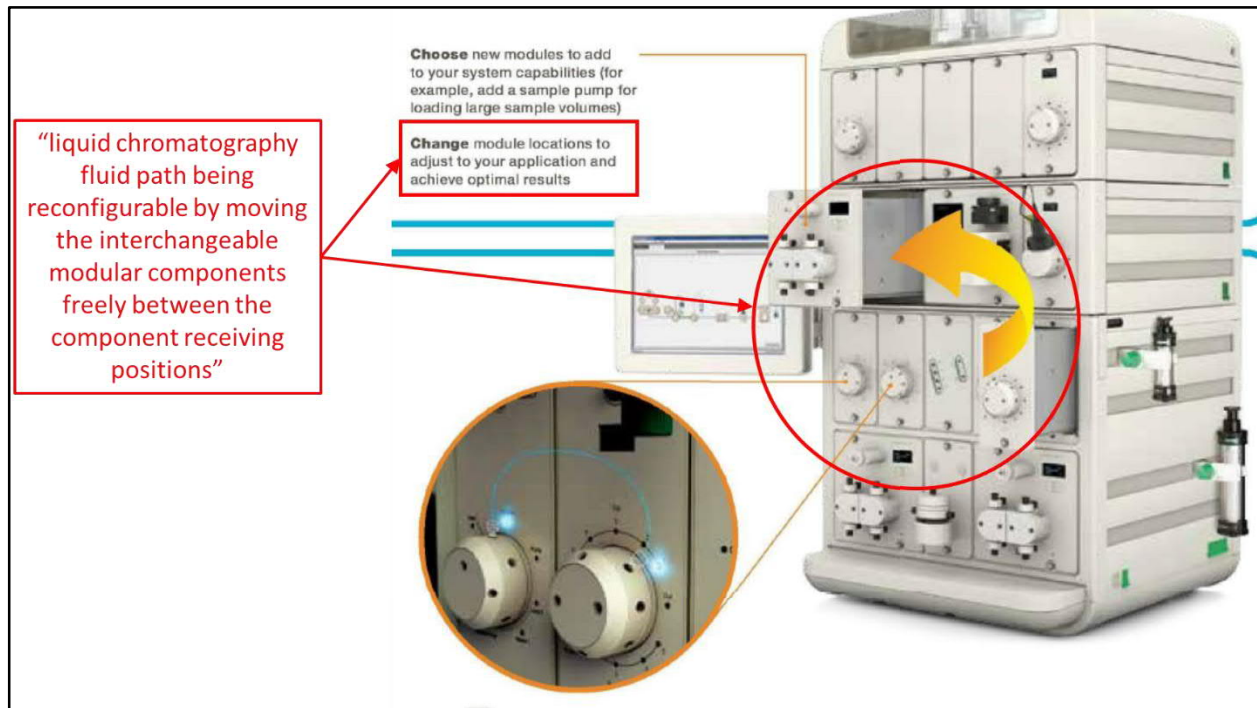
1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. If necessary, disconnect all tubing lines to and from the module that you plan to replace or reposition.
3. Loosen the captive screws on the front of the installed module.
4. Firmly grasp both screws on the module and pull it forward out of its bay.

See Ex. 5, p. 233. See also *Id.* at 234-239.

292. Bio-Rad also markets this feature, as seen in its marketing collateral. Here is one example:



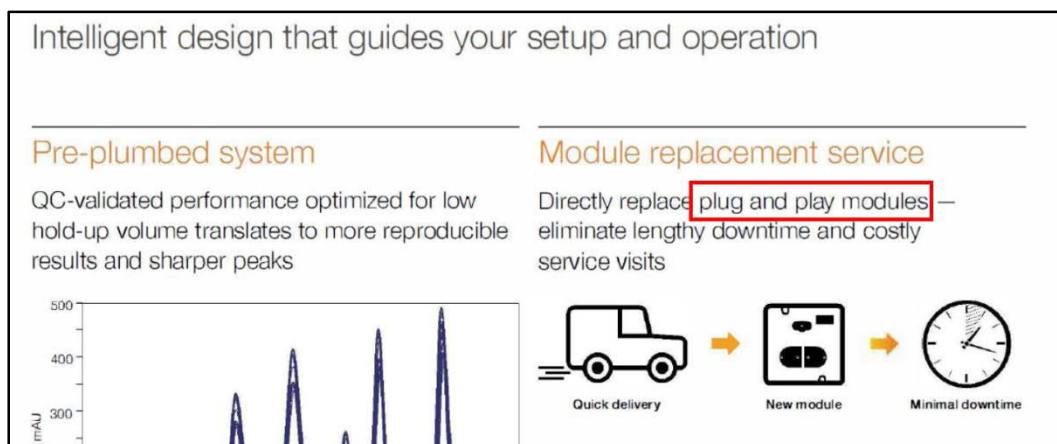
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*NGC Chromatography Systems - Comprehensive Solutions For Protein Purification*

(Ex. 21 (BRGEDEL293539). This same document refers to Bio-Rad's modules as

"plug and play:"



Ex. 21, p. BRGEDEL293542.

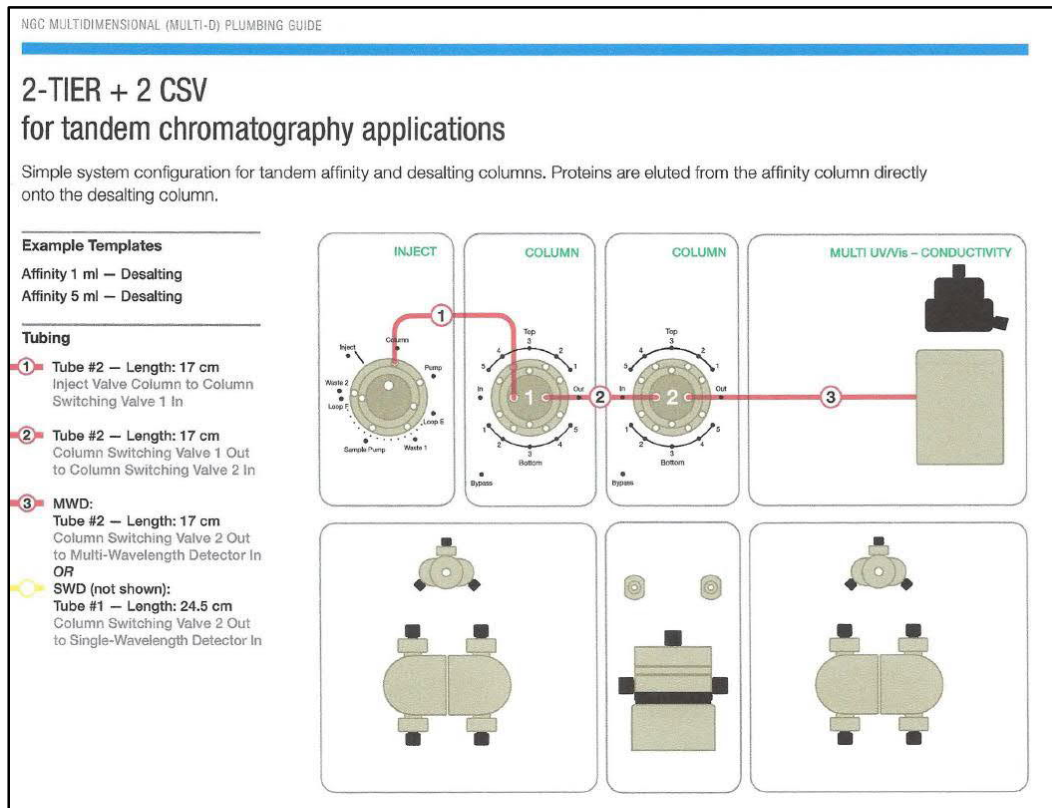
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293. Also, Exhibit 22, entitled *NGC Chromatography Systems - Multidimensional (Multi-D) Plumbing Guide*, further indicates that modules can be placed in different locations:

This guide is designed to help plumb your NGC System for multidimensional (Multi-D) chromatography applications. These techniques can help enhance sample recovery and improve productivity by minimizing the steps and time required for protein purification. In addition, it shows the optimal locations for module placement to minimize tubing length and swept volume.

Ex. 22, p. 2. Indeed, the setup on p. 2, for “2-tier + 2 CSV for tandem chromatography applications,” shows a module arrangement that differs from the standard Quest and Scout configurations:

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Ex. 22, p. 3.

294. In sum, all NGC models fall within the scope of this claim element.

**D. '124 Patent**

**1. Claim 16**

- a. A liquid chromatography system arranged to provide a controlled fluid flow through a chromatography column, the system comprising**

295. Bio-Rad's NGC system (all models) is a liquid chromatography system: Bio-Rad's documents are replete with statements saying as such. One example is in the NGC Instrument Guide:



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296. See Exhibit 5, p. 22 and Exhibit 21, p. BRGEDEL293539.

**b. a housing and**

297. See e.g., Section VIII.A.1.b

**c. two or more interchangeable fluid handling units,**

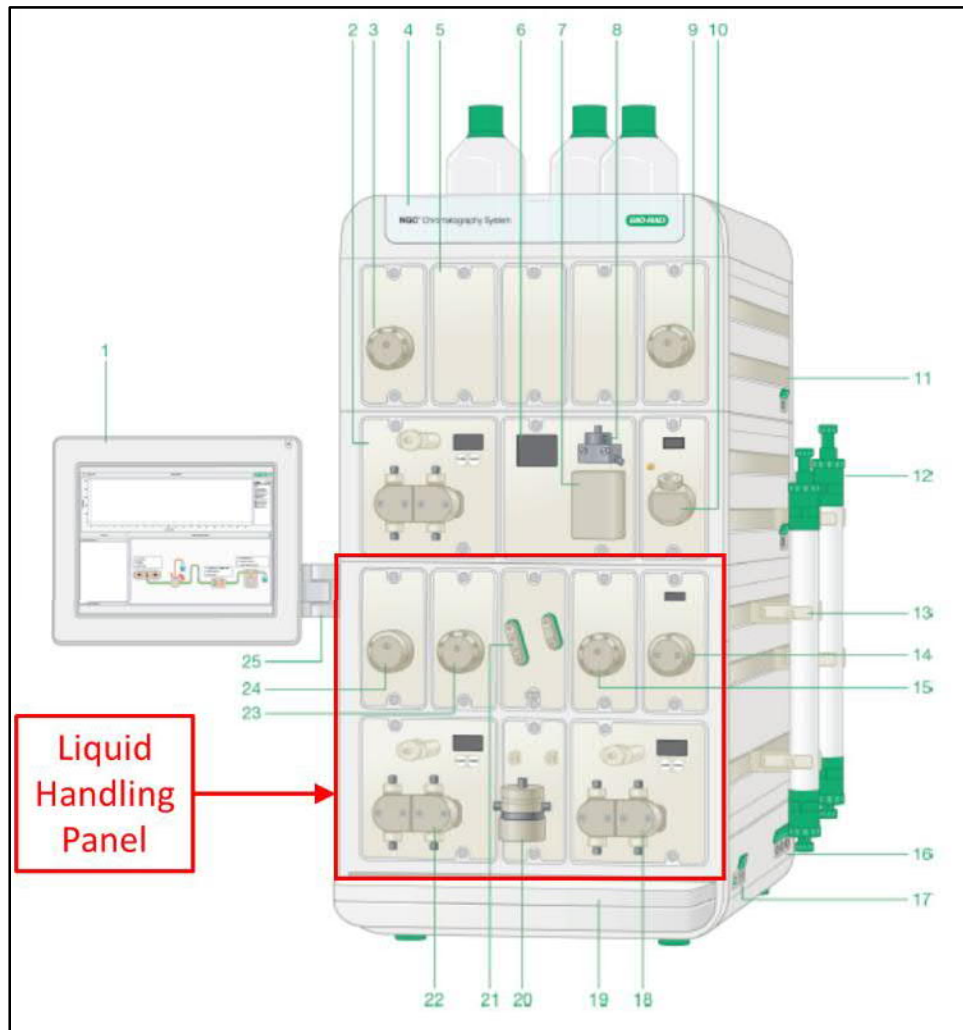
298. See e.g., Section VIII.A.1.d. Note that Section VIII.A.1.d recites “three or more fluid handling units arranged as interchangeable modular components.” Because claim 16 recites the need for only two of such interchangeable fluid handling units, it is broader (putting aside that claim 1 of the ’420 patent requires that they be arranged interchangeable modular components, a requirement recited in a later element of claim 16) , and all of Bio-Rad’s NGC models fall within the scope of this claim element for the same reason as discussed in Section VIII.A.1.d.

**d. the housing comprising a liquid handling panel including two or more component positions for receiving said interchangeable units,**

299. Each of Bio-Rad’s NGC system models has a “liquid handling panel.”

Below is an annotated a figure from Bio-Rad’s Instrument Guide showing this:

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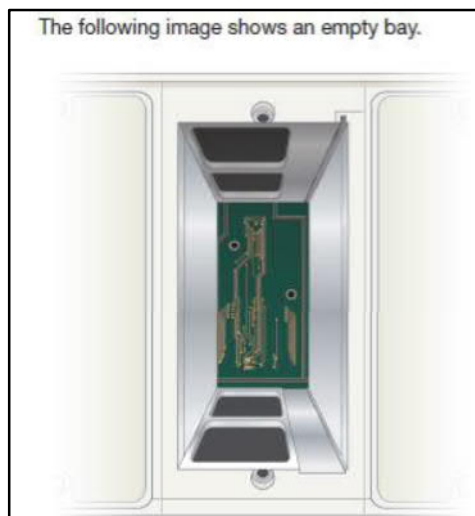


Ex. 5, p. 22. As can be seen in the above illustration from Bio-Rad's documentation, the liquid handling panel has "two or more component positions for receiving said interchangeable units." Note that a portion of the liquid handling panel is hidden by the panel members of the modules. The following illustration from Bio-Rad's Instrument Guide provides a view of a portion of the NGC liquid handling panel:

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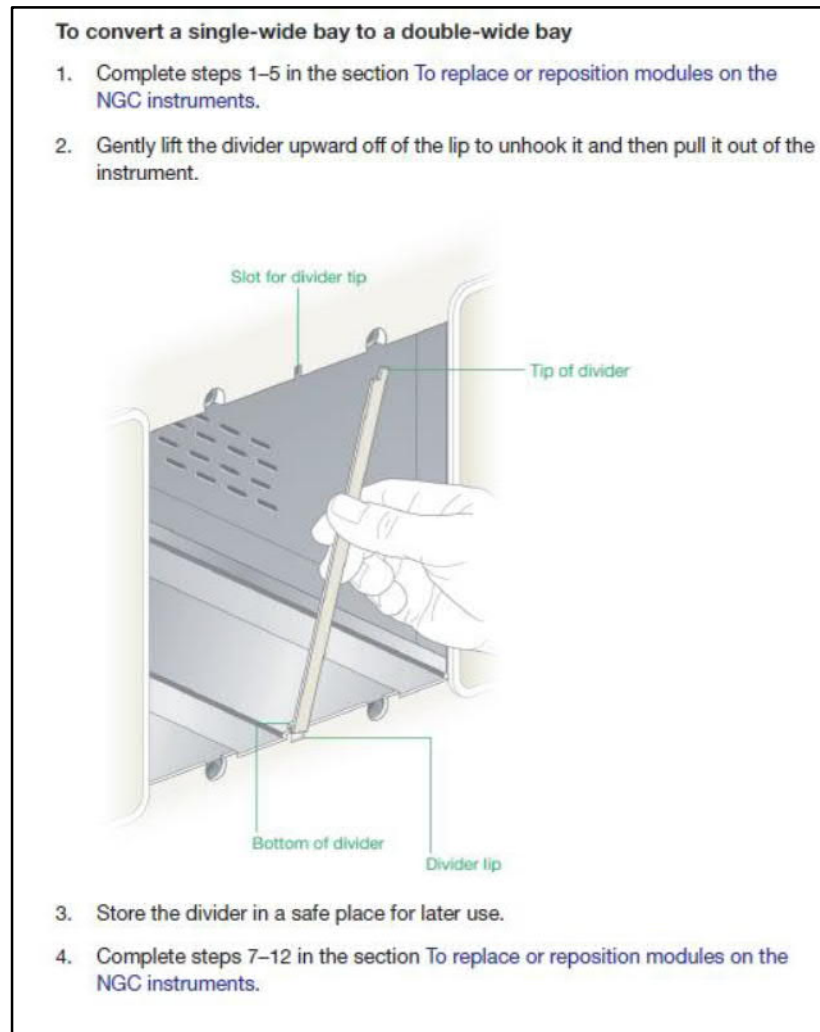
Ex. 5, p. 237. Another view is as follows:



Ex. 5, p. 234. The below illustration shows how to convert a single-wide bay to a double-wide bay:



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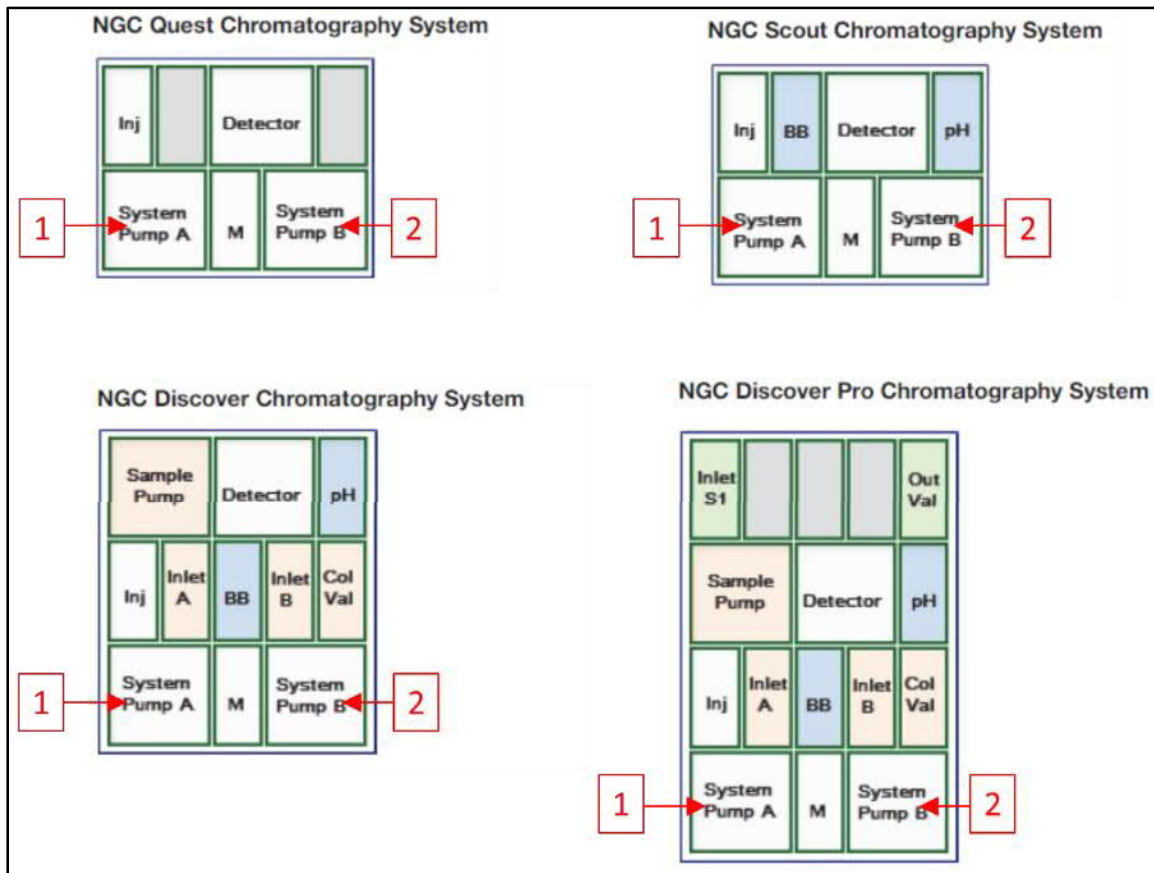
Ex. 5, p. 238.

300. The housing used in all models can accommodate up to ten modules and thus can have up to ten “component receiving positions,” which satisfies the “at least four” requirement. As I discussed above, the size of Bio-Rad’s “bays” can be changed to be single-wide or double-wide bays, meaning depending on Bio-Rad’s customer choice, the housing can accommodate as many as 10 receiving positions



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(i.e., without using any double wide modules). Regardless, the below annotated version of figures from Bio-Rad's Instrument Guide shows two positions:



See Ex. 5, p. 90-91.

301. Thus, all NGC models meet this claim limitation.

**e. wherein said units are arranged as interchangeable modular components, and include:**

302. See e.g., Section VIII.A.1.d. Note that Section VIII.A.1.d recites “three or more fluid handling units arranged as interchangeable modular components.”

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Because claim 16 recites the need for only two interchangeable modular components, it is broader, and all of Bio-Rad's NGC models fall within the scope of this claim element for the same reason as discussed in Section VIII.A.1.d.

**f. a fluidics section;**

303. See Section VIII.A.1.e.

**g. a non fluidics section in turn comprising electronics or electrical components or control means; and**

304. See Section VIII.A.1.f.

**h. a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel, and**

305. See Section VIII.A.1.h. Further, the panel member of Bio-Rad's interchangeable modular components, e.g., the two system pump modules that are supplied with each NGC model, are "arranged ... for attachment of the modular component to a component position of the liquid handling panel." As discussed, the panel members for Bio-Rad's modules comprises, among other things, what Bio-Rad calls a "front plate" having an overlay affixed to the front plate portion on the external side of the system. Bland Tr. 151:4:-155:21. Mr. Chapman testified as follows regarding the purpose of the faceplate and overlay:

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Chapman Tr. 386:13-387:17. Mr. Chapman's testimony is confirmed by referring to Bio-Rad's instructions to its customers for inserting modules:

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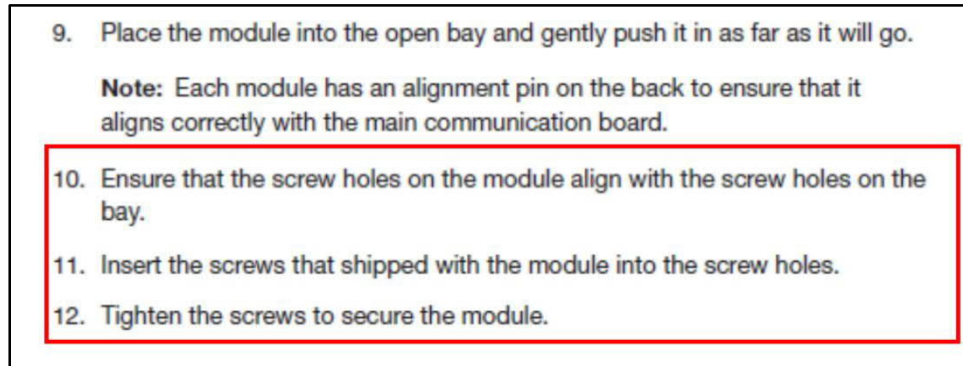
- 
9. Place the module into the open bay and gently push it in as far as it will go.
- Note:** Each module has an alignment pin on the back to ensure that it aligns correctly with the main communication board.
10. Ensure that the screw holes on the module align with the screw holes on the bay.
11. Insert the screws that shipped with the module into the screw holes.
12. Tighten the screws to secure the module.

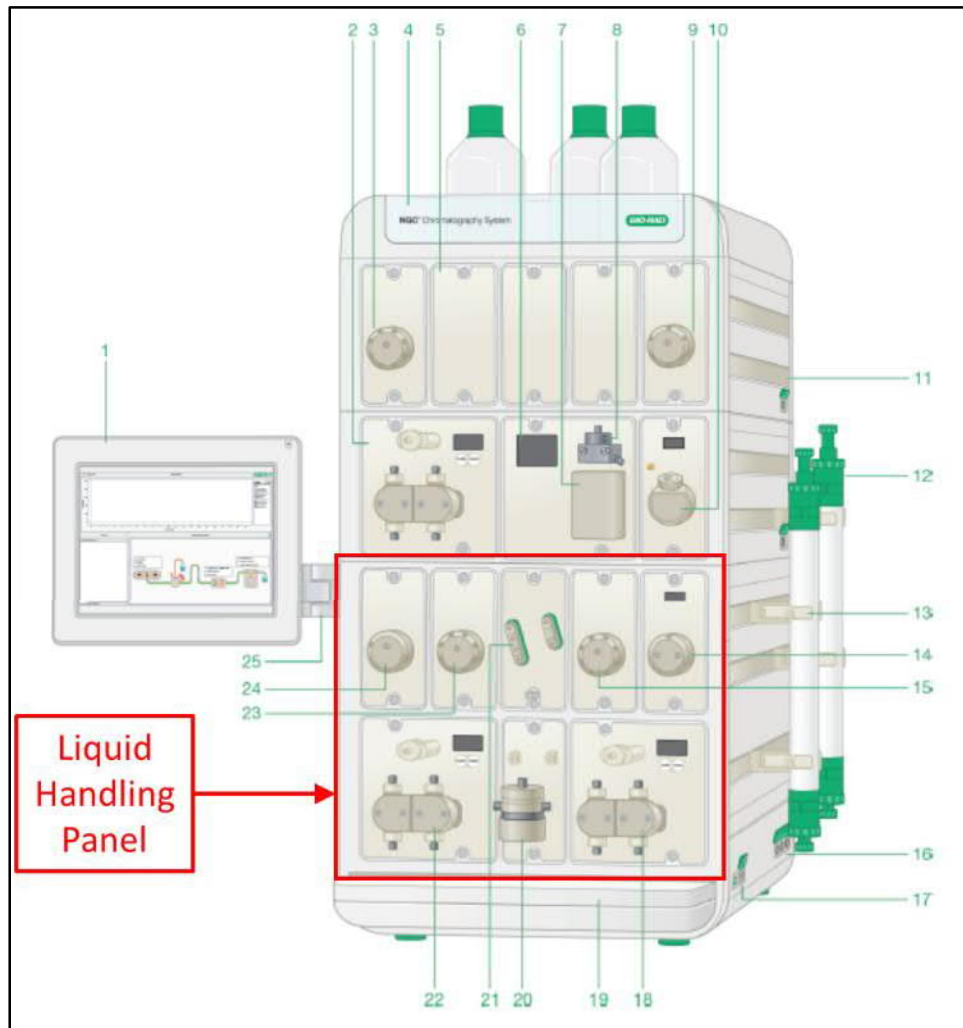
Exhibit 5, p. 235.

306. In sum, all NGC models fall within the scope of this element.

- i. **wherein the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and**

307. All Bio-Rad NGC models fall within the scope of this element. As seen in the below from Bio-Rad's Instrument Guide, the fluidics sections of the two interchangeable modular components, e.g, system pump modules, are external to the housing;

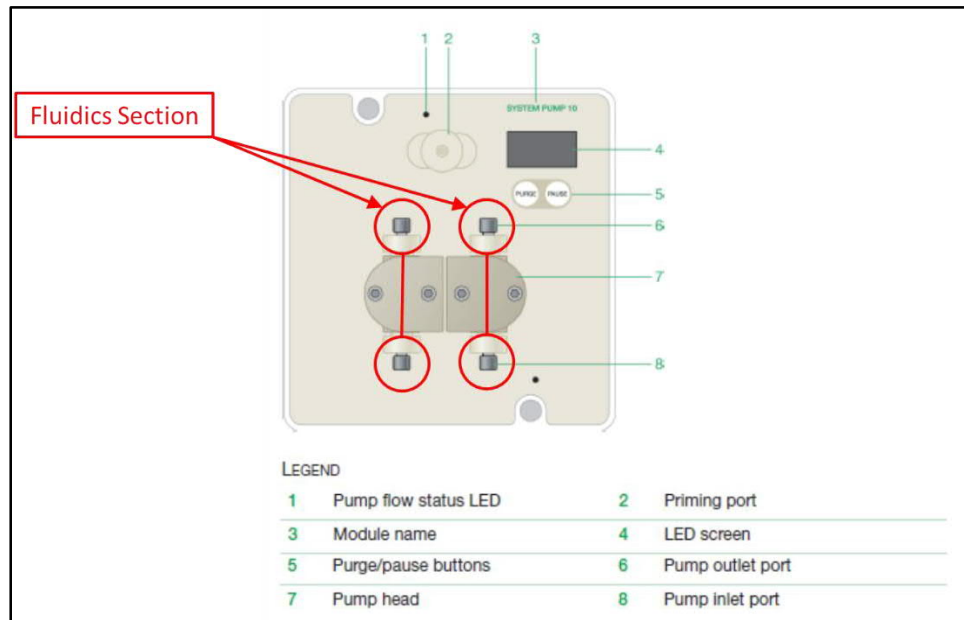
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Ex. 5, p. 22.

308. Bio-Rad's system pump modules, which qualify as the interchangeable modular components for this claim, are such that the "fluidics sections are external to the housing." As discussed, the fluidics section for the system pumps are seen below:

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Ex. 5, pp. 28-29.

309. Note that this figure is annotated to show hidden portions of the fluidics section, *i.e.*, a simplified illustration of the flow path within the fluidics section.

Indeed, the specification for Bio-Rad's system pump modules says [REDACTED]

[REDACTED]

[REDACTED]

Ex. 13 (BRGE0096090) ([REDACTED])

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310. Mr. Chapman testified that this specification was met for the pump modules (Chapman Tr. 529:12-530:17).

311. Thus, each NGC model falls within the scope of this claim element.

**j.      respective non fluidics sections are internal to the housing.**

312. Likewise, as discussed, the specification for system pump modules specify that they have a “non-fluidics section” because they state that [REDACTED]

[REDACTED]

[REDACTED] The specifications further state that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

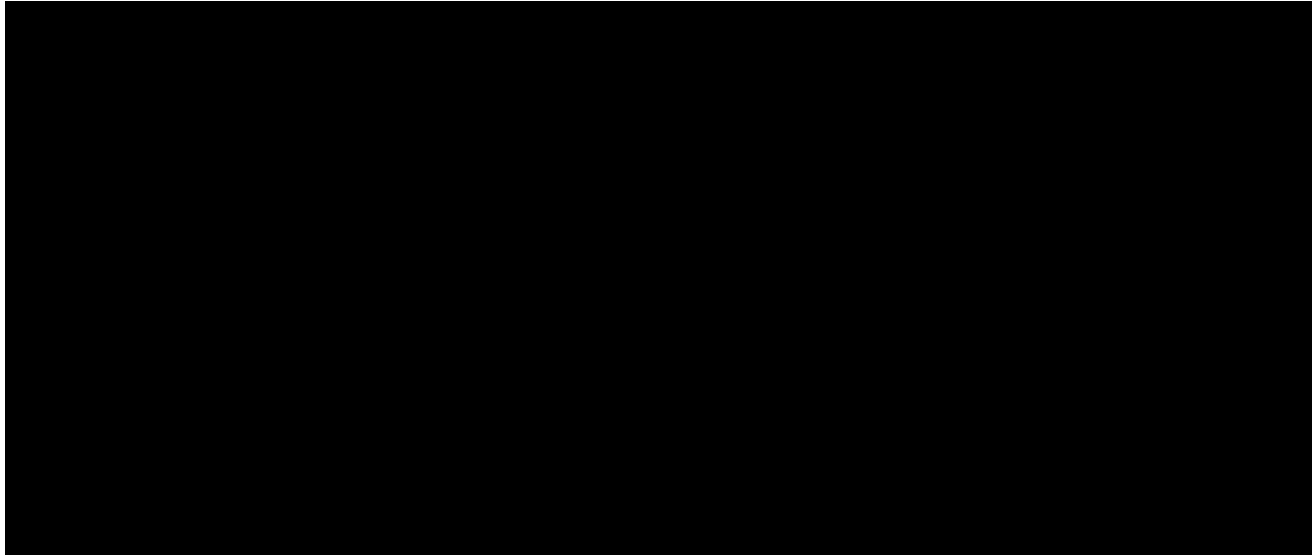
[REDACTED]

Ex. 13 (BRGE0096090) ([REDACTED])

313. As discussed, Mr. Chapman testified that this specification was met. See Chapman Tr. 529:12-530:17.

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314. The NGC Service Manual further demonstrates that there is a non-fluidics section that is internal to the housing.



Ex. 16 (BRGEDEL317444, BRGEDEL317555).

315. Thus, all Bio-Rad NGC models infringe this claim.



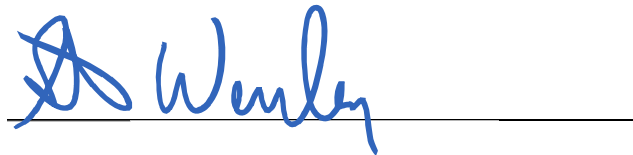
HIGHLY CONFIDENTIAL (TECHNICAL) - ATTORNEYS' EYES ONLY

**IX. CONCLUSION**

316. For the reasons stated above, it is my opinion that Bio-Rad infringes the Asserted Claims.

317. I declare under penalty of perjury under the laws of the United States of America that the foregoing is a true and correct statement of my opinions and the supporting facts and that this declaration was executed on December 15, 2020 at West Lafayette Indiana.

Dated: December 15, 2020



Steven Wereley, Ph.D.

## EXHIBIT A



**STEVEN T. WERELEY, PH.D.**

Professor, Mechanical Engineering

Birck Nanotechnology Center

Purdue University

Phone: (765) 494-5624

[wereley@purdue.edu](mailto:wereley@purdue.edu)

<https://engineering.purdue.edu/~wereley/>

**Mailing/Physical Addresses**

Birck Nanotechnology Center, Room 2019 1205 West State Street West Lafayette, IN 47907-1205 Fax: (765) 496-6443	Mechanical Engineering, Room 1077 585 Purdue Mall West Lafayette, IN 47907-2088 Fax: (765) 494-0539
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**Research Interests**

Micro and Nanoscale fluid mechanics (*microfluidics*), MEMS, bio-MEMS, biological flows at the cellular level, micro-scale laminar mixing, physiological sensors, electrical and optical manipulation of particles and fluids, development of microfluidic diagnostic techniques.

**Education**

**Ph.D. Mechanical Engineering, Northwestern University, Evanston IL, 1997.** Dissertation Topic: An investigation of the physics underlying rotating filtration using particle image velocimetry (PIV), computational particle tracking, and analytical methods.

**M.S. Mechanical Engineering, Northwestern University, Evanston, IL, 1992.** Thesis Topic: A laser Doppler velocimetry (LDV) investigation of the velocity profiles developed in the annulus between differentially rotating cylinders.

**B.S. Mechanical Engineering, Washington University, St. Louis, MO, 1990.** Concentration in fluid mechanics: incompressible flow, compressible flow, and computational fluid dynamics.

**B.A. Physics, Lawrence University, Appleton, WI, 1990.** Physics curriculum (mechanics, electricity and magnetism, electronics, optics, quantum mechanics, experimental methods) combined in equal parts with liberal arts courses.

**Work Experience**

**Professor**, School of Mechanical Engineering, Purdue University (2010-Present). Taught Mechanical Engineering courses at the graduate and undergraduate levels and instructed graduate students in a lab setting.

**Alexander von Humboldt Fellow**, Universität der Bundeswehr, Munich, Germany, Sept.-Oct, 2014.

**Associate Professor**, School of Mechanical Engineering, Purdue University (2005-2010). Taught Mechanical Engineering courses at the graduate and undergraduate levels and instructed graduate students in a laboratory environment.

**Alexander von Humboldt Fellow**, Universität der Bundeswehr, Munich, Germany, June-July 2009.

**Alexander von Humboldt Fellow**, Technische Universität Darmstadt, Darmstadt, Germany, Mar.-Aug., 2007.

**Assistant Professor**, School of Mechanical Engineering, Purdue University (1999-2005). Taught Mechanical Engineering courses at the graduate and undergraduate levels and instructed graduate students in a laboratory environment.

**Post Doctoral Research Scientist**, Mechanical and Environmental Engineering Dept., University of California Santa Barbara (1997-1999). Designed and constructed microfluidics experiments and developed custom particle image velocimetry algorithms specifically tailored to microfluidics applications.

**Currently Active Consulting Areas**

Fluid mechanics measurements using particle image velocimetry (PIV) and other techniques

Fluid mechanics measurements in Microelectromechanical Systems (MEMS), bio-MEMS, and microscopic biological systems using micro-particle image velocimetry ( $\mu$ PIV) and related techniques

Oil spills, oil flows, other fluid spills; Custom-written PIV software and routines

Expert witness services for fluid mechanics, microfluidics, bio fluid mechanics, MEMS, bio-MEMS, and oil spill issues

## Books (Monographs)

**M. Raffel, C. Willert, S. Wereley, J. Kompenhans**, Particle Image Velocimetry: A Practical Guide, 3<sup>rd</sup> ed., Springer, New York (2018). (ISBN 978-3-319-68851-0; <https://doi.org/10.1007/978-3-319-68852-7>)  
**N.T. Nguyen, S.T. Wereley and M. Shaegh**, Fundamentals and Applications of Microfluidics, Artech House, Boston, (1<sup>st</sup> ed. 2002; 2<sup>nd</sup> ed. 2006; 3<sup>rd</sup> ed. 2019). (ISBN 978-1-58053-972-2)

## Books (Edited Collections)

**B. Bhusan (Wereley, section editor)**, Encyclopedia of Nanotechnology, Springer, New York, 2012. (ISBN: 978-90-481-9750-7)

**CH Ahn, M Gijs, S Hardt, SG Kandlikar, JP Landers, Y Lin, A De Mello, H Morgan, NF de Rooij, ST Wereley, and RJ Yang** (section eds), Encyclopedia of Microfluidics and Nanofluidics (ed-in-chief Dongqing Li), Springer, New York (2008).

**R. Bashir and S.T. Wereley** (vol. eds), BioMEMS and Biomedical Nanotechnology (series ed M. Ferrari): Vol. 4: Biomolecular Sensing, Processing and Analysis, Kluwer, Boston (2007). (ISBN 978-0387255668)

## Book Chapters

14. **C Snoeyink and ST Wereley**, "Micro/nano flow characterization techniques," in Handbook of Nanotechnology (Springer, 2012).
13. **HS Chuang, A Kumar, SJ Williams, ST Wereley**, "Optoelectrically-enabled multiscale manipulation," in Handbook of Nanotechnology (Springer, 2012).
12. **JS Kwon, R Thakur and ST Wereley**, "Rapid electrokinetic patterning," in Handbook of Nanotechnology (Springer, 2012).
11. **CD Meinhart and ST Wereley**, "Micro Particle Velocimetry," Chapt. 7 in Micro/Nano Technology Systems for Bio-medical Applications-Microfluidics, Optics and Surface Chemistry, (ed. Chih-Ming Ho), Oxford University Press, Oxford UK (2010). ISBN13: 978-0-19-921969-8; ISBN10: 0-19-921969-9
10. **HS Chuang, A Kumar, ST Wereley**, "Optical flow characterization- micro particle image velocimetry ( $\mu$ PIV)," in Methods in Bioengineering: Microfabrication and Microfluidics (eds Lee and Zahn), Artech House, Boston (2009). ISBN 978-1-59693-401-6
9. **A Kumar, AH Ewing, and ST Wereley**, "Optical tweezers for manipulating cells and particles", Encyclopedia of Microfluidics and Nanofluidics (ed. Dongqing Li), Springer, New York (2008).
8. **P Chamrath, A Kumar, J Cao, and ST Wereley**, "Fundamentals of Diffusion in microfluidic systems", Encyclopedia of Microfluidics and Nanofluidics (ed. Dongqing Li), Springer, New York (2008).
7. **P Chamrath and ST Wereley**, "Micro-PIV-Based Diffusometry," Encyclopedia of Microfluidics and Nanofluidics (ed. Dongqing Li), Springer, New York (2008).
6. **J. Cao and S.T. Wereley**, "Micro-Particle Image Velocimetry in Biomedical Applications," in Encyclopedia of Biomaterials and Biomedical Engineering, 2<sup>nd</sup> edition, (eds G.E. Wnek and G.L. Bowlin), Informa Healthcare, New York (2008).
5. **I. Whitacre and S.T. Wereley**, "Particle Dynamics in a Dielectrophoretic Microdevice", in BioMEMS and Biomedical Nanotechnology (series ed M. Ferrari): Vol. 4: Biomolecular Sensing, Processing and Analysis (vol. eds R. Bashir and S.T. Wereley), Kluwer, Boston (2007).
4. **S.T. Wereley and C.D. Meinhart**, "Electrokinetics in Microdevices" in Complex Systems Science in BioMedicine, eds. Deisboeck, Kresh, Kepler, Kluwer, Boston (2006).
3. **S.Y. Lee, J. Jang, and S.T. Wereley**, "Optical Diagnostics to Investigate the Entrance Length in Microchannels," in MEMS Handbook, ed. Mohamed Gad-el-Hak, Springer, New York (2006).
2. **S.T. Wereley and C.D. Meinhart**, "Micron-Resolution Particle Image Velocimetry" in Micro- and Nano-Scale Diagnostic Techniques, ed. Kenny Breuer, Springer-Verlag, New York, (2005).
1. **C.D. Meinhart, S.T. Wereley, and J.G. Santiago**, "Micron-Resolution Velocimetry Techniques," Laser Techniques Applied to Fluid Mechanics, R. J. Adrian et al. (Eds.), Springer-Verlag, Berlin, pp. 57-70, (2000).

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84. TJ Moehling, DH Lee, ME Henderson, MK McDonald, PH Tsang, S Kaakeh, ES Kim, ST Wereley, TL Kinzer-Ursem, KN Clayton, JC Linnes, "A smartphone-based particle diffusometry platform for sub-attomolar detection of *Vibrio cholerae* in environmental water," Biosensors and Bioelectronics, Vol 167, pp 112497 (2020) <https://doi.org/10.1016/j.bios.2020.112497>

83. X Pan, JS Kwon, JW Khor, SM Mehdi Shamsi, ST Wereley, "Experimental and computational study of optically-driven electrothermal vortex," *Prog. Comp. Fluid Dyn.*, Vol. 19, p. 307-315 (2019).
82. X Kou, PWS Heng, LW Chan, ST Wereley, MT Carvajal, "Effect of Roughness on the Dispersion of Dry Powders for Inhalation: a Dynamic Visualization Perspective," *AAPS PharmSciTech*, Vol. 20 (7), p. 271 (2019).
81. **W Ren, SI Mohammed, ST Wereley and J Irudayaraj**, "Magnetic Focus Lateral Flow Sensor for Detection of Cervical Cancer Biomarkers," *Anal. Chem.*, Vol. 91, 2876–2884 (2019).  
<http://dx.doi.org/10.1021/acs.analchem.8b04848>
80. **KN Clayton, TJ Moehling, DH Lee, ST Wereley, JC Linnes, and TL Kinzer-Ursem**, "Particle Diffusometry: An Optical Detection Method for *Vibrio cholerae* Presence in Environmental Water Samples," *Scientific Reports*, Vol. 9, Article number: 1739 (2019). (2019) 9:1739 |  
<https://doi.org/10.1038/s41598-018-38056-7>
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### Conference Presentations and Papers *26 invited or keynote*

190. **KN Clayton, TJ Moehling, D Lee, K Byers, M Henderson, A Witten, G Berglund, R Preston, ST Wereley, JC Linnes, TL Kinzer-Ursem**, "Development of a New Method and Platform for Point-of-Care Pathogen Detection," Society for Laboratory Automation and Screening, San Diego, California, February 5, 2018. Poster.
189. **KN Clayton, TJ Moehling, ST Wereley, JC Linnes, TL Kinzer-Ursem**, "Development of a New Method and Platform for Point-of-Care Pathogen Detection," Society for Laboratory Automation and Screening, San Diego, California, 2018. Poster.
188. **KN Clayton, TJ Moehling, D Lee, GD Berglund, AJ Witten, ST Wereley, JC Linnes, TL Kinzer-Ursem**, "Detecting Pathogens with Viscosity-Based Measurements," Miniaturized Systems for Chemistry and Life Sciences ( $\mu$ TAS), Savannah, Georgia, 2017. Oral Presentation.
187. **KN Clayton, TJ Moehling, GD Berglund, AJ Witten, D Lee, ST Wereley, JC Linnes, TL Kinzer-Ursem**, "A Viscosity-Based Measurement System for Pathogen Detection," American Institute of Chemical Engineers, Minneapolis, MN, 2017. Oral Presentation.
186. **KN Clayton, TJ Moehling, AJ Witten, GD Berglund, D Lee, ST Wereley, JC Linnes, TL Kinzer-Ursem**, "A Viscosity-Based Measurement System for Pathogen Detection," Biomedical Engineering Society, Phoenix, AZ, 2017. Oral Presentation.
185. **KN Clayton, ST Wereley and TL Kinzer-Ursem**, "Implementation of Particle Diffusometry for Bionanotechnology Measurements and Applications," International Conference on Bioengineering and Nanotechnology (Chicago, IL) 2017. (*Poster contest winner*)
184. **JC Ndukaife, AG Agwu Nnanna, AV Kildishev, VM Shalaev, ST Wereley (Invited)**, Alexandra Boltasseva, "Shaping the future of plasmon nano-optical tweezing", (Gordon Research Conference on Plasmonics and Nanophotonics, 2016)
183. **ST Wereley (Plenary Keynote)**, "Opto-electric Droplet and Particle Physics," Joint Symposium of the 18th Annual Conference of Chinese Society of Micro & Nano Technology and Microsystems & Nanoengineering Summit 2016 (CSMNT2016 & MAN2016), July 28–31, 2016 (Beijing, China).
182. **ST Wereley (Keynote)**, "Visualizing Microscale Electrothermal Vortices," International Symposium on Flow Visualization, June 19-22, 2016 (Gatlinburg, TN).
181. **ST Wereley**, "Droplet and Particle Technologies: Entrepreneurship Opportunities," The Second North Latitude 45 ° Innovative Entrepreneurial Forum, June 15-17, 2016 (Harbin, China).
180. **ST Wereley (Keynote)**, "," International Conference of Microfluidics, Nanofluidics and Lab-on-a-Chip, June 10-12, 2016 (Dalian, China).
179. **ST Wereley (Invited)**, "Non-contact Micro/Nano Object Manipulation," TechConnect World Innovation Conference and Expo 2016, May 23-25, 2016 (National Harbor, Maryland).
178. **Justus C. Ndukaife, A. G. Agwu Nnanna, Alexander V. Kildishev, Vladimir M. Shalaev, Steven T. Wereley, Alexandra Boltasseva**, "On-demand rapid transport and stable trapping of nanoparticles by a hybrid electrothermoplasmonic nanotweezer", (presented at SPIE Optics and Photonics 2016)
177. **Justus C. Ndukaife, A. G. Agwu Nnanna, Alexander V. Kildishev, Vladimir M. Shalaev, Steven T. Wereley, Alexandra Boltasseva**, "Controlled Rapid Delivery and On-chip Trapping of Nanoparticles by a Hybrid Electrothermoplasmonic Nanotweezer", (presented at CLEO 2016)

176. **Justus C. Ndukaife, A. G. Agwu Nnanna, Vladimir M. Shalaev, Steven T. Wereley, Alexandra Boltasseva**, "The hybrid electrothermoplasmonic nanotweezer: A new paradigm in nanomanipulation", (presented at MRS Spring Meeting, Phoenix, AZ, March 2016)
175. **Justus C. Ndukaife, A. G. Agwu Nnanna, Steven T. Wereley, Vladimir M. Shalaev, Alexandra Boltasseva**, "Plasmo-fluidic Device for On-chip Concentration, Manipulation and Sensing of Particles using TiN Plasmonic Nanoantenna Array", (presented at MRS Fall Meeting, Boston, MA, December 2015)
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173. **Justus C. Ndukaife, A. G. Agwu Nnanna, Alexandra Boltasseva, Steven T. Wereley**, "Versatile Plasmo-fluidic Device for Long-range Transport and On-chip Capture of Particles", (oral presentation at 11th International Symposium on PIV, Santa Barbara, CA September 14-16, 2015)
172. **Justus C. Ndukaife, Alexander V. Kildishev, A. G. Agwu Nnanna, Steven T. Wereley, Vladimir M. Shalaev, Alexandra Boltasseva** (*Invited*), "Electrothermoplasmonic Flow for Plasmon-assisted Optical Trapping", (invited talk for 2015 SPIE Conference on Plasmonics: Metallic Nanostructures and Their Optical Properties XIII, San Diego, California, USA, August 9-13, 2015)
171. **Justus C. Ndukaife, Alexander V. Kildishev, A. G. Agwu Nnanna, Steven T. Wereley, Vladimir M. Shalaev, Alexandra Boltasseva**, "Hybrid Electroplasmonic Nanotweezer (HENT): Versatile Plasmo-fluidic Device for On-chip Capture, Manipulation and Printing of Particles on Plasmonic Hotspots", (poster presented at Summer School on Complex Photonics at the International School of Physics, Enrico Fermi, Varenna, Italy, July 13-18, 2015)
170. **Justus C. Ndukaife, Alexander V. Kildishev, A. G. Agwu Nnanna, Steven T. Wereley, Vladimir M. Shalaev, Alexandra Boltasseva**, "Versatile Plasmo-fluidic Device for On-chip Concentration, Manipulation and Sensing of Particles in Suspensions", (poster presented at the Gordon Research Conference on Microfluidics, Mount Snow, VT, June 2015)
169. **Justus C. Ndukaife, Alexander V. Kildishev, A. G. Agwu Nnanna, Steven T. Wereley, Vladimir M. Shalaev, Alexandra Boltasseva**, "Plasmon-Assisted Optoelectrofluidics", (oral presentation AW3K.5, CLEO /A&T Topical Review - Optofluidics Microsystems I, 2015 Conference, San Jose, CA, USA, May 10-15, 2015)
168. **Justus C. Ndukaife, Avnish Mishra, Urcan Guler, A. G. Agwu Nnanna, Steven T. Wereley, Alexandra Boltasseva**, "Photothermal heating enabled by plasmonic nanoantennas for electrokinetic manipulation and sorting of submicron particles", (oral presentation FTh1K.2, CLEO 2014, San Jose, CA, USA, June 8-13, 2014)
167. **Justus C. Ndukaife, Avnish Mishra, Urcan Guler, A. G. Agwu Nnanna, Steven T. Wereley, Alexandra Boltasseva**, "Thermoplasmonics for Optofluidics", NSF Center for Photonics and Multiscale Nanomaterials IRG2 Review Meeting, March 28, 2014, Purdue University, W/L, USA
166. **Justus C. Ndukaife, Avnish Mishra, Urcan Guler, A. G. Agwu Nnanna, Steven T. Wereley, Alexandra Boltasseva**, "A new Plasmo-fluidic Device for On-chip Concentration, Manipulation and Sorting of Particles on a Plasmonic Substrate", (NSF Center for Photonics and Multiscale Nanomaterials All-Hands Meeting, September 26, 2014, University of Michigan, Ann Arbor, USA)
165. **K Clayton, A Mishra and ST Wereley**, "Rapid Electrokinetic Patterning for Vertical Stacking and Manipulation of Particles," Pres. #R10.00009, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (San Francisco, CA, Nov. 2014).
164. **A Mishra, S Williams and ST Wereley**, "Electrokinetic Patterning of Metal Nanoparticles and Nanowires," Pres. #R10.00006, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (San Francisco, CA, Nov. 2014).
163. **R Thakur, A Amin and ST Wereley**, "Convection-diffusion driven concentration gradients in nanolitre droplets for microfluidic screening applications," Pres. #D10.00001, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (San Francisco, CA, Nov. 2014).
162. **JW Khor, A Mishra, X Pan and ST Wereley**, "Investigation of Material Dependence in Electrothermal Vortex," Pres. #A10.00004, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (San Francisco, CA, Nov. 2014).
161. **SJ Williams, A Mishra, V Velasco and ST Wereley**, "Electrothermal Flow Patterns Generated by Resistive Heaters", 12th International Conference on Nanochannels, Microchannels, and Minichannels, Chicago, USA, August 3-7, 2014.

160. **JC Ndukaife, A Mishra, U Guler, AA Nnanna, ST Wereley, and A Boltasseva**, "Photothermal heating enabled by plasmonic nanoantennas for electrokinetic manipulation and sorting of submicron particles," CLEO, San Jose, USA, June 8-13, 2014.
159. **A Mishra, V Kulkarni, JW Khor and ST Wereley**, "Low Interfacial Tension Measurement with Synthetic Schlieren Imaging," Pres. # E32.00001, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (Pittsburgh, PA, Nov. 2013).
158. **ST Wereley and A Mishra**, "Hybrid Opto-electric Manipulation of Macromolecules," Pres. # E6.00001, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (Pittsburgh, PA, Nov. 2013).
157. **SJ Williams, V Velasco, A Mishra, J-S Kwon, and ST Wereley**, "Rapid electrokinetic patterning (REP): manipulating colloids from nanoparticles to bacteria," 2013 Kentucky Nano Symposium, Louisville, KY, Aug. 16-17, 2013.
156. **C Snoeyink and ST Wereley**, "Bessel Beam Microscopy: Three Dimensional Particle Tracking with Super-Resolution," Particle Image Velocimetry 2013 (Delft, The Netherlands 1-3 July, 2013).
155. **A Mishra, V Kulkarni, JW Khor and ST Wereley**, "Surface Tension Induced Meniscus Measurement using Free Surface Synthetic Schlieren," Particle Image Velocimetry 2013 (Delft, The Netherlands 1-3 July, 2013).
154. **ST Wereley (Invited)**, "Opto-electric Manipulation of Particles and Droplets," 8th World Conference on Experimental Heat Transfer, Fluid Mechanics and Thermodynamics *ExHFT-8* (June 16-20, 2013 Lisbon, Portugal).
153. **JS Kwon, ST Wereley**, "Theoretical and Experimental Characterization of an Electrothermal Microfluidic Flow," Advances in Microfluidics and Nanofluidics (Notre Dame, IN, May 24-26, 2013).
152. **A Mishra, K Clayton, R Thakur, SJ Williams, A Kumar, ST Wereley**, "Rapid Optoelectrokinetic Manipulation of Nanoparticles," Advances in Microfluidics and Nanofluidics (Notre Dame, IN, May 24-26, 2013).
151. **JS Kwon, V Velasco, SJ Williams, ST Wereley**, "Rapid Electrokinetic Patterning Technique for Manipulation of Colloids and Microorganisms and its Technical Advancement," Advances in Microfluidics and Nanofluidics (Notre Dame, IN, May 24-26, 2013).
150. **JS Kwon, V Velasco, SJ Williams, ST Wereley**, "Rapid Electrokinetic Patterning Technique for Manipulation of Colloids and Microorganisms, and its Technical Advancement," 2nd European Optical Society Conference on Optofluidics *EOSOF 2013* (Munich, Germany, May 13-15, 2013).
149. **A Mishra, R Thakur, SJ Williams, A Kumar, ST Wereley**, "Optoelectrokinetic trapping of Gold Nanoparticles," 2nd European Optical Society Conference on Optofluidics *EOSOF 2013* (Munich, Germany, May 13-15, 2013).
148. **ST Wereley (Invited)**, "A Multiscale Suite of Particle and Droplet Manipulation Technologies," ASME/IMECE, IMECE2012-85373, Houston, TX, Nov 2012.
147. **JS Kwon and ST Wereley**, "A new dimensionless variable for electrothermal microfluidic flow," ASME/IMECE, IMECE2012-94082, Houston, TX, Nov 2012.
146. **JP Kim, JS Kwon and ST Wereley**, "Experimental Results of Electrothermal Vortex in Parallel ITO-glass with High Conductivity Medium and AC electric field and Laser," ASME/IMECE, IMECE2012-94075, Houston, TX, Nov 2012.
145. **C Park and ST Wereley**, "Twin Vortex Flow Generation under a Non-Uniform Alternating Electric Field and Optical Illumination," IMECE2012-93989, ASME/IMECE, Houston, TX, Nov 2012. *Best poster, Fluids Engineering Division, Micro Nano Forum.*
144. **C Park and ST Wereley**, "AC electrokinetic flow generation with various types of electrodes," ASME/IMECE, IMECE2012-87858, Houston, TX, Nov 2012.
143. **ST Wereley (Invited)**, "Lab on a Chip Applications of Optoelectric Particle and Droplet Manipulation," ICNMM2012-73268, 10<sup>th</sup> International Conference on Nanochannels, Microchannels, and Minichannels, July 2012, Puerto Rico.
142. **JS Kwon and ST Wereley**, "μPIV characterization of a toroidal microfluidic vortex driven by opto-electrokinetic methods," Abstract D18.05, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (Baltimore, MD, Nov. 2011).
141. **ST Wereley**, "Random uncertainty estimates of PIV measurements using correlation statistics," Abstract H26.02, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (Baltimore, MD, Nov. 2011).
140. **JS Kwon and ST Wereley**, "INVESTIGATION FOR TOROIDAL MICROFLUIDIC VORTICES GENERATED BY A LASER ILLUMINATION APPLICATION IN AN UNIFORM ELECTRIC FIELD," IMECE/ASME, IMECE2011-62743, Denver, CO, Nov. 2011.

139. **K Han, ST Wereley, JH Oh, Z Zhang**, "STUDY ON FACTORS IN COFFEE-RING STRUCTURE FORMATION USING PIV METHOD," IMECE/ASME, IMECE2011-63231, Denver, CO, Nov. 2011.
138. **SJ Williams, JS Kwon, SP Ravindranath, J Irudayaraj, and ST Wereley**, "Rapid concentration and manipulation of colloids and microorganisms through double layer polarization electrokinetics," poster T32A, 15<sup>th</sup> International Conference on Miniaturized Systems for Chemistry and Life Sciences (Micro-TAS, Seattle, WA, Oct 2011).
137. **ST Wereley (invited)**, "Software Programmable Lab-on-a-Chip Applications and Optimization," Lab-on-a-Chip World Congress (San Francisco, CA, Sep 2011).
136. **R Thakur, SJ Williams, R Cohn, J Rathfon, JF Berret, M Yan, ST Wereley**, "Patterning of non-spherical particles onto electrode surface: Study of orientation behavior under viscous fluid and AC electrokinetic forces," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (Long Beach, CA, Nov. 2010).
135. **C Snoeyink and ST Wereley**, "A Novel 3 Dimension 3 Component Micro-PIV System," Pres. # RW.00007, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (Long Beach, CA, Nov. 2010).
134. **C Park and ST Wereley**, "Using TEM For the Nano-scale Particle Image Velocimetry," IMECE/ASME, IMECE2010-38835, Vancouver, CA, Nov. 12-18, 2010.
133. **JS Kwon, S Ravindranath, A Kumar, J Irudayaraj, and ST Wereley**, Application of an optically induced electrokinetic manipulation technique on live bacteria," IMECE/ASME, IMECE2010-39324, Vancouver, CA, Nov. 12-18, 2010.
132. **R Thakur and ST Wereley**, "Optically Induced Rapid Electrokinetic patterning of Non-spherical particles- Study of The Colloidal Phase Transition," IMECE/ASME, IMECE2010-39665, Vancouver, CA, Nov. 12-18, 2010.
131. **SJ Williams and ST Wereley**, "Experiments and simulation of a dielectrophoretically oscillating microparticle," Paper 1598, Proceedings of the 15<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal), July 5-8, 2010.
130. **JS Kwon, A Kumar, SJ Williams and ST Wereley**, "A study for opto-electrokinetic forces of colloidal particles on an electrode surface using Voronoi and Delaunay tessellation," Paper 1775, Proceedings of the 15<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal), July 5-8, 2010.
129. **A Kumar, C Cierpka, SJ Williams, C J Kahler and ST Wereley**, "3D3C velocimetry measurements of an electrothermal microvortex using wavefront deformation PTV and a single camera," Paper 1594, Proceedings of the 15<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal), July 5-8, 2010.
128. **ST Wereley (invited)**, "Microscale Velocity and Temperature Measurement Techniques," American Institute of Aeronautics and Astronautics 40<sup>th</sup> Fluid Dynamics Conference (June 28-July 1, 2010, Chicago, IL).
127. **Smith, C.T., Thakur, R., Chuang, H.S., Kumar, A., Wereley, S.T.**, "A hybrid optoelectric device for multi-scale particle and droplet manipulation," Proceedings of SPIE, Vol.7762, pp.68, June, 2010.
126. **HS Chuang, A Kumar, CT Smith, and ST Wereley**, "Rapid and dynamic multiscale manipulation based on a hybrid optoelectric device," Trends in Optical Micromanipulation II, Innsbruck, Austria, April 11-16, 2010.
125. **ST Wereley, SJ Williams, A Kumar, CH Chuang, JS Kwon and CT Smith (invited)**, "Opto-electric Manipulation of Droplets and Colloids for Material Assembly," Materials Research Society Spring Meeting (San Francisco, CA April 6-8, 2010).
124. **HS Chuang and ST Wereley (invited)**, "Microfluidic gas purge valves," MNHMT/ASME, MNHMT2009-18534, Shanghai, China, Dec. 18-21, 2009.
123. **A Kumar, SJ Williams, and ST Wereley** "Micro and nano particle manipulation using optically modulated electrokinetic flows" ASME 2009 Micro/Nanoscale Heat and Mass Transfer International Conference, MNHMT2009-18493 Shanghai, China, Dec. 18-21, 2009. (*Awarded "Excellent Paper" distinction—3 given among 340 submissions*)
122. **HS Chuang, A Kumar, and ST Wereley**, "Light-Enabled Droplet Manipulations," Gallery of Fluid Motion, APS/DFD 62nd Annual Meeting, Minneapolis, MN, USA, Nov. 22-24, 2009. (APS highlighted video)
121. **HS Chuang, ST Wereley, and SC Jacobson**, "An automated cyclic particle extractor," IMECE/ASME, IMECE2009-10422, Lake Buena Vista, FL, USA, Nov. 13-19, 2009.
120. **A Kumar, SJ Williams, JS Kwon, NG Green, NK Yip, and ST Wereley**, "Optically induced rapid electrokinetic patterning: a study of the operational regimes and dominant forces" *Proc. ASME/IMECE*, Lake Buena Vista, FL, Nov. 13-19, 2009.



119. **SJ Williams**, A Kumar, ST Wereley, "Continuous colloidal concentration and patterning with optically induced AC electrokinetics" *2009 AIChE Annual Meeting, Annual Meeting of the American Electrophoresis Society*, Nashville, TN, Nov. 8-13, 2009.
118. **ST Wereley**, (*invited*), "Massively parallel opto/electric manipulation of colloidal particles," *Laser Science XXV* (Oct. 11-15, 2009, San Jose, CA).
117. **ST Wereley** (*invited*), "Micrometer and nanometer spatial resolution with  $\mu$ PIV," 25 Years of Particle Image Velocimetry in Aerodynamics (Sept. 23-25, 2009, Göttingen, Germany).
116. A Kumar, **SJ Williams**, and ST Wereley, "A novel optically driven electrokinetic technique for manipulating nanoparticles" *SPIE Symposium on SPIE Nanoscience + Engineering*, Vol. \*7400\*, paper 74000V, (San Diego, CA, Aug. 2-6, 2009).
115. **SJ Williams**, A Kumar, and **ST Wereley**, "Optically induced electrohydrodynamics and electrokinetic colloidal aggregation" *Proc. ASME/FEDSM*, Paper#2009-78121 (Vail, CO), Aug. 2-6, 2009.
114. **SJ Williams** and **ST Wereley**, "Hydrodynamic investigations of a dielectrophoretically trapped and agitated microparticle" *Proc. ASME/FEDSM*, Paper#2009-78068 (Vail, CO), Aug. 2-6, 2009.
113. **ST Wereley**, E Judokusumo, A Kumar, and **SJ Williams** (*invited*), "Velocity Fields in Electrooptically-Induced Fluid Flows," *Proc. Seventh Int. ASME Conf. on Nanochannels, Microchannels and Minichannels* (June 22-24, 2009, Pohang, South Korea).
112. A Kumar, **SJ Williams** and **ST Wereley**, "Optically Modulated Rapid Electrokinetic Patterning For Micro and Nano Particles," *Proc. European Conferences on Biomedical Optics*, Vol. \*7371\*, paper 737110 (14-18 June 2009, Munich, Germany).
111. **ST Wereley**, **SJ Williams**, and A Kumar (*invited*), "Optoelectric Micro/Nano Particle Manipulation for Biological Applications," presented at the LifeChips 2009 Symposium (UC-Irvine, Jan. 2009).
110. **ST Wereley** (*invited*), "Flow Diagnostics for Micro/Nano Device Characterization," presented at the International Conference on Fascinating Advancement in Mechanical Engineering 2009 (Mepco-Schlenk Engineering College, Sivakasi, TN, India, Dec. 2008).
109. **SJ Williams**, SD Peterson, A Kumar, and **ST Wereley**, "Three dimensional transport of an optically induced electrothermal microvortex," *Pres. # LN.00003*, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (San Antonio, TX, Nov. 2008).
108. E Judokusumo, A Kumar, **SJ Williams**, and **ST Wereley**, "Analysis of Optically Induced Fluid Flows in Electric Fields," *Proc. ASME/IMECE* 2008-66935 (October 31-November 6, 2008 Boston, 2008, Boston).
107. **HS Chuang**, A Amin, M Thodentoddi, T Vijaykumar, S Jacobson, and **ST Wereley**, "POLYDIMETHYLSILOXANES (PDMS) PERISTALTIC PUMP CHARACTERIZATION FOR PROGRAMMABLE LAB-ON-A-CHIP APPLICATIONS", *Proc. 12th International Conference on Miniaturized Systems for Chemistry and Life Sciences ( $\mu$ TAS2008)*, San Diego, USA, Oct 12-16, 2008.
106. A Kumar, **SJ Williams**, and **ST Wereley**, "Rapid electrokinetic patterning of colloids using optical landscapes" *Proc. 12<sup>th</sup> International Conference on Miniaturized Systems for Chemistry and Life Sciences ( $\mu$ TAS2008)*, San Diego, USA, Oct 12-16, 2008.
105. **SJ Williams**, P Chamарthy and **ST Wereley**, "Laser-Induced Fluorescence Thermometry for Joule Heating in AC Electrokinetic Chips," *Proc. ASME-FED* paper # 55175 (Jacksonville, FL, Aug. 10-14), 2008.
104. **SJ Williams**, A Kumar and **ST Wereley**, "Rapid colloidal assembly with optically induced electrokinetic forces," presented at University Government Industry Micro/nano Symposium, Louisville, KY, July 13-16, 2008.
103. R Nasarek, **ST Wereley**, P Stephan, "Flow field measurements near a moving meniscus of a capillary flow with micro Particle Image Velocimetry ( $\mu$ PIV), *Proc. of the Sixth International Conference on Nanochannels, Microchannels, and Minichannels*, Darmstadt, Germany, June 23-25, 2008.
102. AM Amin, M Thottethodi, TN Vijaykumar, **ST Wereley** and SC Jacobson, "Automatic Volume Management for Programmable Microfluidics," *Programming Language Design and Implementation Conference* (Tucson, AZ), paper #13, June 7-13, 2008.
101. Z Huang, **HS Chuang**, **ST Wereley** and **MK Banks**, "Effect of biofilm surface roughness on thickness of hydrodynamic boundary layer and coefficient of friction," *Paper Coll-476*, American Chemical Society Spring Meeting (New Orleans, LA), Apr. 6-10, 2008.
100. A Kumar, NK Yip and **ST Wereley**, "Particle transport on periodic potential landscapes," *Pres. # EA.00004*, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (Salt Lake City, UT, Nov. 2007).
99. P Chamарthy, **ST Wereley** and SV Garimella, "Microscale laser-induced fluorescence method for non-intrusive temperature measurement," *Proc. ASME/IMECE*, Paper #2007-41935 (Seattle, WA), Nov. 11-15, 2007.

98. **H.S. Chuang and S.T. Wereley**, "In-Vitro Wall Shear Stress Measurements for Microfluid Flows by using Second-order SPE micro-PIV," Proc. ASME/IMECE, Paper #2007-41171 (Seattle, WA), Nov. 11-15, 2007.
97. **R. Muddu and S.T. Wereley**, "Numerical Simulation of Optical Trap systems," Proc. ASME/IMECE, Paper #2007-42411 (Seattle, WA), Nov. 11-15, 2007.
96. **S.J. Williams, S.T. Wereley**, "Field Flow Analysis of Dielectrophoretically Suspended Particles," Proc. ASME/IMECE, Paper #2007-41252 (Seattle, WA), Nov. 11-15, 2007.
95. **A.M. Amin, M. Thottethodi, T.N. Vijaykumar, S.T. Wereley and S.C. Jacobson**, "Aquacore: A General-Purpose Architecture for Programmable Microfluidics," paper T33C,  $\mu$ YAS (Paris, France), Oct. 7-11, 2007.
94. **H.S. Chuang and S.T. Wereley**, "Nanometer-resolution and second-order accurate SPE micro-PIV," 7<sup>th</sup> International Symposium on Particle Image Velocimetry (Rome, Italy), Sept. 11-14, 2007.
93. **A.M. Amin, M. Thottethodi, T.N. Vijaykumar, S. Wereley and S.C. Jacobson**, "AquaCore: A programmable Architecture for Microfluidics," Proc. 34th Annual International Symposium on Computer Architecture (ISCA) (San Diego, CA), pages 254-265, June 10-13, 2007.
92. **S.T. Wereley (invited)**, "Interesting Problems in Microflows," Schloß Dagstuhl-Seminar 07121: *Experimental Fluid Mechanics, Computer Vision & Pattern Recognition* (International Conference and Research Center for Computer Science, Wadern, Germany), March 18 – 23, 2007.
91. **A.H. Ewing, S. Kim; S.T. Wereley**, "Mediating Fluidic Self- Assembly with optical traps," Proc. AIChE Annual Meeting, paper 35E, (San Francisco, CA) Nov. 12-17, 2006.
90. **S.T. Wereley (keynote)**, "Micro and Nanoscale Flow Measurement," 33<sup>rd</sup> National and 3<sup>rd</sup> International Conference on Fluid Mechanics and Fluid Power (Mumbai, India), Dec. 7-9, 2006.
89. **A. Kumar, V. Gorti, S.T. Wereley**, "Biological Agent Detection Using Optical Diffusometry Methods," Proc. ASME/IMECE, Paper #2006-13267 (Chicago, IL), Nov. 5-10, 2006.
88. **H.K. Dhavaleswarapu, P. Chamrathy, S.V. Garimella, J.Y. Murthy, and S.T. Wereley**, "Experimental Investigation of Thermocapillary Convection near an Evaporating Meniscus," Proc. ASME/IMECE, Paper #2006-13901 (Chicago, IL), Nov. 5-10, 2006.
87. **P. Chamrathy, S.T. Wereley and S.V. Garimella**, "Simultaneous Measurement of Temperature and Velocity Using  $\mu$ PIV," Proc. ASME/IMECE, Paper #2006-14079 (Chicago, IL), Nov. 5-10, 2006.
86. **H.-S. Chuang, S. T. Wereley**, "Study of Single Pixel Evaluation for Experimental Measurements in a Microchannel," Proc. ASME/IMECE, Paper #2006-14517 (Chicago, IL), Nov. 5-10, 2006.
85. **C. Park, S.T. Wereley, O. Campanella, D.E. Nivens, K.M. Little, H. Sumali**, "Measurements of Mechanical Properties of Human Red Blood Cells," Proc. ASME/IMECE, Paper #2006-15175 (Chicago, IL), Nov. 5-10, 2006.
84. **S.T. Wereley (invited)**, "Micro and Nanoscale Flow Measurement and Visualization," Proceedings of the 12<sup>th</sup> International Symposium on Flow Visualization (Göttingen, Germany), Sept. 10-14, 2006.
83. **P. Chamrathy, H.K. Dhavaleswarapu, S.V. Garimella, J.Y. Murthy and S.T. Wereley**, "Visualization of convection patterns near an evaporating meniscus using  $\mu$ PIV," Proceedings of the 12<sup>th</sup> International Symposium on Flow Visualization (Göttingen, Germany), Sept. 10-14, 2006.
82. **H.-S. Chuang, S. T. Wereley, C. D. Meinhart, D. Tretheway**, "Single pixel evaluation PIV for nano-resolution flow measurements," paper number 32.4, Proceedings of the 13<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal), June 26-29, 2006.
81. **P. Chamrathy, S.T. Wereley and S.V. Garimella**, "Simultaneous Measurement of Temperature and Velocity using Cross-Correlation  $\mu$ PIV," paper number 12.4, Proceedings of the 13<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal), June 26-29, 2006.
80. **A.R. De Carlo, M. Rokkam, A. ul Haque, S.T. Wereley, P.P. Irazoqui, H.W. Wells, W.T. McLamb, S.J. Roux, D.M. Porterfield**, "Development of a Microfluidic Ion Sensor Array (MISA) to Monitor Gravity-Dependent Calcium Fluxes in Ceratopteris Spores," Abstract #56, Annual Meeting of the American Society for Gravitational and Space Biology (Reno, NV, November 1-4, 2005).
79. **M. Rokkam, P. P. Irazoqui, A. R. De Carlo, S. T. Wereley, H.W. Wells, W.T. McLamb, D.M. Porterfield**, "Development and testing of an amplifier array for interfacing multichannel digital data acquisition and *in silico* cell physiology MEMS sensor devices," Institute of Biological Engineering Annual Meeting (Tucson, AZ, March 8-12, 2006).
78. **A. ul Haque, A. R. De Carlo, M. Rokkam, S.T. Wereley, H.W. Wells, W.T. McLamb, S.J. Roux, D.M. Porterfield**, Design, fabrication and characterization of an *in silico* cell physiology lab for measuring cellular responses to microgravity, Institute of Biological Engineering Annual Meeting. March 8-12, 2006

77. **A. ul Haque, A. R. De Carlo, M. Rokkam, S.T. Wereley, H.W. Wells, W.T. McLamb, S.J. Roux, D.M. Porterfield**, Design, fabrication and characterization of an in silico cell physiology lab for measuring cellular responses to microgravity. International MEMS conference. Singapore, May 9-12, 2006
76. **J. Cao and S.T. Wereley**, "Shear-induced migration of dilute Brownian suspensions," Pres. # EC.00007, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (Chicago, IL, Nov. 2005).
75. **P. Chamarthy and S.T. Wereley**, "Temperature Measurement using Brownian Motion in the Presence of a Velocity Gradient," Pres. # BB.00008, Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting (Chicago, IL, Nov. 2005).
74. **S.T. Wereley and C.D. Meinhart**, "Spatial Resolution and Errors of Single Pixel Interrogation," Proc. ASME/IMECE, Paper #2005-83065, (Orlando, FL, Nov. 2005).
73. **P. Chamarthy, S. Wereley, S. V. Garimella**, "Assessment of Alternate Approaches for Temperature Measurement using Brownian Motion," 6th International Symposium on Particle Image Velocimetry (Pasadena, CA, Sept. 21-23, 2005).
72. **J. Cao, S. T. Wereley**, "PIV Measurement in Capillary Tube Flow and Measurement Error Due to Multi-pixel Window Correlation," 6th International Symposium on Particle Image Velocimetry (Pasadena, CA, Sept. 21-23, 2005).
71. **S.T. Wereley, C.D. Meinhart, D. Tretheway, L. Gui, A. Sud**, "Bias and Random Errors in Single Pixel Interrogation," 6th International Symposium on Particle Image Velocimetry (Pasadena, CA, Sept. 21-23, 2005).
70. **S.T. Wereley**, "Optical Diagnostics for Nanoscale Flow Problems?" First International Nanofluidics Workshop (Boekelo, The Netherlands, April 18-20 2005).
69. **S.T. Wereley (keynote)**, "Progress and Current Developments in Micro-PIV," Joint International PIVNET II / ERCOFTAC Workshop on Micro PIV and Applications in Microsystems (Delft, The Netherlands, April 7-8, 2005).
68. **L. Karp-Boss, P.A. Jumars, P. Grant, S.T. Wereley, and E.H. Klingler**, "Motion of diatoms in steady and unsteady shear flows," ASLO 2005 Aquatic Sciences Meeting (Salt Lake City, Utah, February 20-25, 2005).
67. **J. Cao and S.T. Wereley**, "Brownian particle distribution in tube flows," Proc. ASME/IMECE, Paper #2004-61899, (Anaheim, CA, Nov. 2004).
66. **S.Y. Lee, J. Jang, and S.T. Wereley**, "Entrance length of Low Reynolds number flow in microchannel," Proc. ASME/IMECE, Paper #2004-61908, (Anaheim, CA, Nov. 2004).
65. **P. Chamarthy and S.T. Wereley**, "Mixing Characteristics in a 2D Serpentine Micro-Channel," Proc. ASME/IMECE, Paper #2004-61902, (Anaheim, CA, Nov. 2004).
64. **S.T. Wereley and I. Whitacre**, "Particle Dynamics in a Dielectrophoretic Microdevice," paper 3.2, Proceedings of the 12<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal), July 12-15, 2004.
63. **D. Liu, S.V. Garimella, and S.T. Wereley**, "Infrared Micro-Particle Image Velocimetry of Fluid Flow in Silicon-Based Microdevices," ASME Heat Transfer/Fluids Engineering Summer Conference (Charlotte, NC), paper number: HT-FED2004-56385, July 2004.
62. **H.A. Diefes-Dux, P.K. Imbrie, K. Haghighi, G.U. Lee, S.T. Wereley, and P. Wankat**, "Nanotechnology Exposure in a First-Year Engineering Program," International Conference on Engineering Education and Research (Olomouc and Bouzov Castle, Czech Republic, June 27-30, 2004).
61. **S.T. Wereley**, "Microfluidic Diagnostics applied to Cold Gas Thruster Design and Analysis," ESA 4<sup>th</sup> International Spacecraft Propulsion Conference (Cagliari, Italy, June 2-4, 2004).
60. **S.T. Wereley, I. Whitacre, R. Bashir and H.B. Li**, "DEP Particle Dynamics and the Steady Drag Assumption," Nanotech 2004 (Boston, March 7-11, 2004).
59. **J. Jang and S. T. Wereley**, "A Capacitive Micro Gas Flow Sensor Based on Slip Flow," IEEE-MEMS 2004 (Maastricht, The Netherlands, January 25-29, 2004).
58. **S.T. Wereley, I. Whitacre, R. Bashir and H.B. Li**, "DEP Particle Dynamics and the Steady Drag Assumption," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, (East Rutherford, NJ, Nov. 2003).
57. **J. Cao and S.T. Wereley**, "The role of Brownian motion in fluid/particulate experiments," Proc. ASME/IMECE, Paper #2003-43360, (Washington, DC, Nov. 2003).
56. **S.Y. Lee and S.T. Wereley**, "Pressure Measurement in the Microchannel using Air Compression," Proc. ASME/IMECE, Paper #2003-41163, (Washington, DC, Nov. 2003).
55. **J. Jang and S.T. Wereley**, "Slip Flow Analyses of Capacitive Pressure-Based Micro Flow Sensor," Proc. ASME/IMECE, Paper #2003-41142, (Washington, DC, Nov. 2003).

54. **G.U. Lee and S.T. Wereley**, "Teaching Nanoscience and Engineering at an Intermediate Level," American Institute of Chemical Engineers Annual Meeting (San Francisco, CA), Nov. 16-21, 2003.
53. **S. Stone, C. D. Meinhart and S. T. Wereley**, "Out of plane spatial resolution of volume illumination PIV using a compound lens system," 5th International Symposium on Particle Image Velocimetry, (Pusan, Korea, Sept. 2003).
52. **Y. H. Kim, S. T. Wereley and C. H. Chun**, "Flow field produced by a vibrating cantilever plate in various geometries," 5th International Symposium on Particle Image Velocimetry, (Pusan, Korea, Sept. 2003).
51. **M.W. Eckerle, C.E. Nyquist, R.L. Schlupf, K. Haghighi, S.T. Wereley**, "Finite Element Modeling of a Micro-Scale Resonant Fan for Microfluidic Transport," ASAE Annual International Meeting, Paper 033098 (Las Vegas, NV, July 2003).
50. **J.Jang, Y. Zhao, and S.T. Wereley**, "Pressure Distributions and TMAC Measurements in Near-Unity Aspect Ratio, Anodically Bonded Microchannels," MEMS 2003, (Kyoto, Japan, Jan. 2003).
49. **S.T. Wereley and I. Whitacre (invited)**, "Velocity Averaging from Out of Plane Gradients in micro-PIV," Paper 2003-0782, American Institute of Aeronautics and Astronautics Annual Meeting, Reno, NV, Jan. 2003.
48. **C.H. Chung and S.T. Wereley**, "Numerical Simulation of Low- Speed Gas Flows in Microchannels," Paper 2003-0860, American Institute of Aeronautics and Astronautics Annual Meeting, Reno, NV, Jan. 2003.
47. **C.H. Chung and S.T. Wereley**, "Analysis of Gas Flows in Microchannels with Small Pressure Difference," Paper 2003-0861, American Institute of Aeronautics and Astronautics Annual Meeting, Reno, NV, Jan. 2003.
46. **S.T. Wereley, S.Y. Lee, and L.C. Gui**, "Entrance Length and Turbulence Transition in Microchannels," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, Dallas, TX, Nov. 2002.
45. **S. Stone, C.D. Meinhart, and S.T. Wereley**, "Out of plane spatial resolution of volume illumination PIV," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, Dallas, TX, Nov. 2002.
44. **C.H. Chung and S.T. Wereley**, "Computation of Rerefied Gas Flows in Microchannels," JSME/KSME Fluids Engineering Conference (Nagoya, Japan, Nov. 2002).
43. **J. Jang, Y. Zhao, S.T. Wereley, and L.C. Gui**, "Mass Flow Measurements of Gases in Deep-RIE Microchannels," Proc. ASME/IMECE, Paper #2002-33779, (New Orleans, LA, Nov. 2002).
42. **S.Y. Lee, S.T. Wereley, L.C. Gui, W.L. Qu, and I. Mudawar**, "Microchannel Flow Measurement using Micro Particle Image Velocimetry," Proc. ASME/IMECE, Paper #2002-33682, (New Orleans, LA, Nov. 2002).
41. **S.T. Wereley and G.U. Lee**, "Teaching Nanotechnology/Nanoscience Across Disciplines," American Institute of Chemical Engineers Annual Meeting (Indianapolis, IN), Nov. 3-8, 2002.
40. **Eric Tkaczyk, Vandna Handa, Sangwoo Lee, Helen McNally, Lichuan Gui, Steve Wereley, Rashid Bashir**, "Determination Of The Charge Attached To Micro-Scale Devices Used In Fluidic Self-Assembly Processes", MRS Fall Meeting (Boston, MA) 2002.
39. **S.T. Wereley (invited)**, "Microfluidic manipulation of particles, cells, viruses, and molecules," BioMEMS and biomedical nanotechnology WORLD 2002, (Columbus, OH), Sept. 6-8, 2002.
38. **C.D. Meinhart, S. Stone, D. Tretheway, S.T. Wereley**, "Spatial Resolution Limits of Micron Resolution Particle Image Velocimetry," Proceeding of the Seiken Symposium on Particle Image Velocimetry (Tokyo, Japan), p. 57-71, August 23, 2002.
37. **S.T. Wereley and V.P. Hohreiter**, "Simultaneous, Spatially-Resolved Temperature and Velocity Measurements Using Cross-Correlation PIV," paper 15.1, Proceedings of the 11<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal), July 8-11, 2002.
36. **L. Gui, S.T. Wereley and S.Y. Lee**, "Digital Filters for Reducing Background Noise in Micro PIV Measurements," paper 12.4, Proceedings of the 11<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal), July 8-11, 2002.
35. **S.T. Wereley, V. Hohreiter, J. Chung**, "Simultaneous, spatially-resolved temperature and velocity measurements in microchannel flows," THERMES 2002: Thermal Challenges in Next Generation Electronic Systems, (Santa Fe, NM), January 13-16, 2002.
34. **Y.H. Kim, S.T. Wereley, C.H. Chun**, "Experimental study on the flow field around a vibrating cantilever plate," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, San Diego, CA, Nov. 2001.
33. **S.T. Wereley, V. Hohreiter, J.N. Chung**, "Simultaneous Temperature and Velocity Measurement," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, San Diego, CA, Nov. 2001.



32. **S. Stone, C.D. Meinhart, S.T. Wereley**, "Using Particle Image Velocimetry to Probe Wall Shapes with Nanoscope Resolution," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, San Diego, CA, Nov. 2001.
31. **S.T. Wereley, C.D. Meinhart, S. Stone, V. Hohreiter, and J. Chung**, Proc. SPIE Int. Soc. Opt. Eng., Vol. 4558, pp. 124-132 (San Francisco, Oct. 2001).
30. **V. Hohreiter, S.T. Wereley, J.N. Chung, M.G. Olsen**, "Cross-correlation analysis for temperature measurement," 4th International Symposium on Particle Image Velocimetry, Paper 1145, Göttingen, Germany, Sept. 2001.
29. **S.T. Wereley and L.C. Gui**, "PIV measurement in a four-roll-mill flow with a central difference image correction (CDIC) method," 4th International Symposium on Particle Image Velocimetry, Paper 1027, Göttingen, Germany, Sept. 2001.
28. **S. Stone, C.D. Meinhart, S.T. Wereley**, "Using  $\mu$ -PIV to Probe Wall Shapes with Nanoscope Resolution," 4th International Symposium on Particle Image Velocimetry, Paper 1143, Göttingen, Germany, Sept. 2001.
27. **S.T. Wereley, C.D. Meinhart, S. Stone, V. Hohreiter, J. Chung**, "A Microfluidic MEMS Characterization Toolbox," International MEMS Workshop 2001, pp. 244-253, Singapore, July 2001.
26. **S.T. Wereley**, "Experiments and Simulations in Micro/Nano Domains," ASME Information Storage and Processing Systems Conference, Santa Clara, CA, June 2001.
25. **S.T. Wereley, L.C. Gui, and C.D. Meinhart (invited)**, "Flow Measurement Techniques for the Microfrontier," Paper 2001-0243, American Institute of Aeronautics and Astronautics Annual Meeting, Reno, NV, Jan. 2001.
24. **C.D. Meinhart and S.T. Wereley (invited)**, "Fluid Mechanics Issues at the Microscale," Paper 2001-0720, American Institute of Aeronautics and Astronautics Annual Meeting, Reno, NV, Jan. 2001.
23. **S.T. Wereley, H. Apple, R. Gomez, R. Bashir**, "Microfluidic Biomedical Device Characterization," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, Washington, DC, Nov. 2000.
22. **C.D. Meinhart, S.W. Stone, and S.T. Wereley**, "A microfluidic-based nanoscope," ICTAM 2000 (Chicago, IL), paper GV-13, Aug. 2000.
21. **S.T. Wereley and C.D. Meinhart**, "Accuracy Improvements in Particle Image Velocimetry Algorithms," paper 13.4, Proceedings of the 10<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal), July 10-13, 2000.
20. **C.D. Meinhart, S. Stone, and S.T. Wereley**, "A Microfluidic-based Nanoscope," Proc.  $\mu$ TAS2000, pp. 83-86, Enschede, The Netherlands, May 2000.
19. **S.T. Wereley, C.D. Meinhart, and M.H.B. Gray**, "Depth Effects in Volume Illuminated PIV," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, New Orleans, LA, Nov. 1999.
18. **S.T. Wereley, C.D. Meinhart, M.H.B. Gray**, "Depth Effects in Volume Illuminated Particle Image Velocimetry," pp. 545-550, The Third International Workshop on Particle Image Velocimetry, Santa Barbara, CA, Sept. 1999.
17. **C.D. Meinhart, S.T. Wereley, and J.G. Santiago**, "A PIV Algorithm for Estimating Time-Averaged Velocity Fields," presented at the Symposium on Optical Methods and Image Processing in Fluid Flow ASME/JSME Fluids Engineering Conference, San Francisco, CA, July 18-23, 1999.
16. **Meinhart CD, Gray MHB, Wereley ST** "PIV Measurements of High-speed flows in Silicon-micromachined nozzles," (AIAA/ASME/SAE/ASEE 35<sup>th</sup> Joint Propulsion Conference and Exhibit, Los Angeles, CA, June 20-24, 1999) AIAA 99-3756.
15. **R.M. Lueptow and S.T. Wereley**, "Particle Distribution in Rotating Filtration," Proc. Amer. Filtration Soc., (Advances in Filtration and Separation Technology, Boston), Vol. 13, 252-259, 1999
14. **S.T. Wereley, C.D. Meinhart, J.G. Santiago, and R.J. Adrian**, "Velocimetry for MEMS Applications," Proc. ASME/DSC, Vol. 66, 453-459, (Micro-fluidics Symposium, Anaheim, CA, Nov. 1998).
13. **S.T. Wereley, C.D. Meinhart, and J.G. Santiago**, "Microfluidic PIV: Algorithms and Experiments," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, Philadelphia, PA, Nov. 1998.
12. **J.G. Santiago, S.T. Wereley, C.D. Meinhart, D.J. Beebe, and R.J. Adrian**, "A Micron-Resolution Particle Image Velocimetry System for Microfluidics," 8<sup>th</sup> International Symposium on Flow Visualization (Sorrento, Italy), Aug. 1998.
11. **C.D. Meinhart, J.G. Santiago, S.T. Wereley, and R.J. Adrian**, "Diagnostic techniques for microfluids research," Proceedings of the 9<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal) paper 6.4 (1998).
10. **J.G. Santiago, C.D. Meinhart, D.J. Beebe, S.T. Wereley, and R.J. Adrian**, "Velocimetry for Microfluidics," Solid State Sensor and Actuator Workshop (Hilton Head, SC), June 1998.

9. **S.T. Wereley, J.G. Santiago, R. Chiu, C.D. Meinhart, and R.J. Adrian**, "Micro-resolution particle image velocimetry," Proc. SPIE, Vol. 3258, pp. 122-133 (Micro- and Nano-Fabricated Structures and Devices for Biomedical Environmental Applications, San Jose, CA, Jan. 1998).
8. **S.T. Wereley and R.M. Lueptow**, "Particle Motion in a Taylor-Couette Filter Device," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, San Francisco, CA, Nov. 1997.
7. **S.T. Wereley and R.M. Lueptow**, "Particle motion in Taylor Couette flow," Proc. ASME/OED Intl. Cong. Sym., Vol 1, pp. 73-80, 1997.
6. **S.T. Wereley and R.M. Lueptow**, "Velocity Field in Wavy Circular Couette Flow," Proc. 10th Int. Couette-Taylor Workshop, July 1997.
5. **S.T. Wereley and R.M. Lueptow**, "Mixing in Wavy Taylor Vortex Flow," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, Nov. 1996.
4. **S.T. Wereley and R.M. Lueptow**, "Velocity Field in Wavy Vortex Flow," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, Nov. 1995.
3. **S.T. Wereley, S.A. Labhsetwar, and R.M. Lueptow**, "Wavy Taylor Vortex Flow: Experimental Velocity Vectors," Gallery of Fluid Motion at the 48th Annual Meeting of the APS/DFD, Nov. 1995.
2. **S.T. Wereley and R.M. Lueptow**, "Measurements of Velocity Fields with Application to Two-Phase Flow in a Taylor-Couette Separator," Proc. 9th Int. Couette-Taylor Workshop, Boulder, CO, Aug. 1995.
1. **S.T. Wereley, R.M. Lueptow, and K. Min**, "An LDV Investigation of the Taylor Vortex Phenomenon," Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, Tallahassee, FL, Nov. 1992.

#### **University/Corporate Invited Seminars**

67. **Optoelectric Micro/Nano Particle and Droplet Manipulation**, presented at Northwestern University, Nov 8, 2012.
66. **PIV Overview**, Graduatekolleg GRK1114 seminar days, Kleinwalsertal, Austria, Jun 18-20, 2012.
65. **Analyzing Disaster: How big was the Deepwater Horizon disaster?**, presented at the Culver Academies, May 24, 2012.
64. **Optoelectric Micro/Nano Particle and Droplet Manipulation**, presented at Purdue Calumet, Water Institute, Sep 20, 2011.
63. **What can we learn about PIV Uncertainty from the correlation shape?**, presented at the PIV Uncertainty Workshop, Las Vegas, NV, May 11-13, 2011.
62. **Optoelectric Micro/Nano Particle and Droplet Manipulation**, presented at Virginia Tech, Apr 27, 2011.
61. **Using HUBzero to Distribute and Enable Analysis of Deepwater Horizon Oil Spill Videos**, Hubzero Workshop, IUPUI, Apr 5 2011.
60. **Optoelectric Micro/Nano Particle and Droplet Manipulation**, presented at Stanford University, Oct 26, 2010.
59. **Assessing Disaster: How much oil flowed from BP's Macondo well?** presented at Stanford University, Oct 27, 2010.
58. **Temperature and Particle Sizing using Brownian Motion**, presented at International Symposium on Micro/Nano Flow Measurement Techniques, Tokyo, Sept 2010.
57. **Optoelectric Micro/Nano Particle and Droplet Manipulation**, presented at The Ohio State University, Feb 26, 2010.
56. **Opto-Electro Particle Manipulation and Diagnostics**, presented at the Danish Technical University, Copenhagen, Denmark, Sept. 22, 2009.
55. **Opto-Electro Particle Manipulation and Diagnostics**, presented at the University of Alberta, Edmonton, Alberta, Canada, Sept. 13, 2009.
54. **Flow Diagnostics and Optoelectric Micro/Nano Particle Manipulation**, presented at the DFG Priority Program SPP 1164 Nano- & Microfluidics, Bad Honnef, Germany, July 30, 2009.
53. **Flow Diagnostics and Optoelectric Micro/Nano Particle Manipulation**, presented at Deutsche Zentrum für Luft- und Raumfahrt (DLR), Cologne, Germany, July 29, 2009.
52. **Flow Diagnostics and Optoelectric Micro/Nano Particle Manipulation**, presented at Technische Universität Braunschweig, Braunschweig, Germany, July 13, 2009.
51. **Flow Diagnostics and Optoelectric Micro/Nano Particle Manipulation**, presented at Universität des Saarlandes, Saarbrücken, Germany, July 7, 2009.
50. **Flow Diagnostics and Optoelectric Micro/Nano Particle Manipulation**, presented at Yonsei University, Seoul, Korea, June 26, 2009.
49. **Flow Diagnostics and Optoelectric Micro/Nano Particle Manipulation**, presented at Korea Institute of Science and Technology (KIST), Seoul, Korea, June 25, 2009.

48. **Flow Diagnostics and Optoelectric Micro/Nano Particle Manipulation**, presented at Chung-Ang University, Seoul, Korea, June 25, 2009.
47. **Flow Diagnostics and Optoelectric Micro/Nano Particle Manipulation**, presented at NYU-Poly, New York, NY, on Feb. 27, 2009.
46. **Flow Diagnostics and Optoelectric Micro/Nano Particle Manipulation**, presented at Columbia University, New York, NY, on Feb. 26, 2009.
45. **Flow Diagnostics and Optoelectric Micro/Nano Particle Manipulation**, presented at Stevens Institute of Technology, Hoboken, NJ, on Feb. 25, 2009.
44. **Optoelectric Micro/Nano Particle Manipulation**, presented at Indian Institute of Technology Madras, India, on Dec. 10, 2008.
43. **Optoelectric Micro/Nano Particle Manipulation**, presented at University of Southampton, Southampton UK, on Oct. 30, 2008.
42. **Optoelectric Micro/Nano Particle Manipulation**, presented at Rutgers University, New Brunswick, NJ, on Oct. 22, 2008.
41. **Flow Diagnostics for Micro/Nano Device Characterization**, presented at Technische Universität Braunschweig, Braunschweig, Germany, on Aug. 14, 2007.
40. **Flow Diagnostics for Micro/Nano Device Characterization**, presented at Universität Heidelberg, Heidelberg, Germany, on July 18, 2007.
39. **Flow Diagnostics for Micro/Nano Device Characterization**, presented at Universität Rostock, Rostock, Germany, on June 29, 2007.
38. **Microfluidics and suitable diagnostic techniques**, presented at Deutsche Zentrum für Luft- und Raumfahrt (DLR), Göttingen, Germany, on June 8, 2007.
37. **What Can We Learn From Diffusion in Microfluidics?**, presented at Johns Hopkins University, Baltimore, MD, Jan. 26, 2007.
36. **Manipulation and detection of nanoparticles using light**, Tools for Nano Engineering (ARO Workshop), Purdue University, Oct. 2-4, 2006.
35. **What is "Nanofluidics"? or The Nano-izing of Fluid Mechanics**, NCN nano-tutorial seminar series, Purdue University, Feb. 20, 2006.
34. **Micro/Nano Fluidics: fundamentals and devices**, presented in S.C. Johnson and Sons Science and Engineering Council, Racine, WI, Feb. 15, 2006.
33. **Introduction to Microfluidics**, presented at the CAMD / CBM2 2005 Summer Workshop, Louisiana State University, Baton Rouge, LA, July 25, 2005.
32. **Micro and Nanoscale Flow Diagnostics**, presented at University of Karlsruhe, Karlsruhe, Germany, April 12, 2005.
31. **Micro and Nanoscale Flow Diagnostics**, presented at Alberts-Ludwig University, Freiburg, Germany, April 13, 2005.
30. **Micro and Nanoscale Flow Diagnostics**, presented at Technical University of Darmstadt, Darmstadt, Germany, April 14, 2005.
29. **Experimental Microfluidics**, presented at Samsung Advanced Institute of Technology, Suwon, South Korea, Sept. 17, 2003.
28. **Experimental Microfluidics**, presented at POSTECH University, Pohang, South Korea, Sept. 18, 2003.
27. **Experimental Diagnostics for Microscale Sensor and Actuator Evaluation**, presented at AFRL Microfluidics Workshop, Los Angeles, CA, May 12, 2003.
26. **Microfluidics of Biomedical Microdevices**, presented at Baxter Healthcare, Round Lake, IL, April 25, 2003.
25. **Algorithm Improvements for Micro-PIV**, presented at TSI, Inc., Minneapolis, MN, April 7, 2003.
24. **Fluid Mechanics in Micro and Nano Domains**, presented at ARO Nanotechnology Workshop, Chicago, IL, Nov. 14, 2002.
23. **Fluid Mechanics and Heat Transfer Research at Purdue**, presented at Schlumberger Mechanical Eureka Community: Mechanical Systems, Dynamics & Design Seminar, Paris, Oct. 1-3 2002.
22. **Experimental Microfluidic Diagnostics and Educating Students and Professionals About Microfluidics**, AIAA Microfluidics Panel Discussion, AIAA Conference, St. Louis, MO, June 26, 2002.
21. **Characterization of Thermo-fluid Processes at MEMS level and the potential use of x-rays**, presented at Argonne National Laboratory, Chicago, IL, March 1, 2002.
20. **Physics Choices**, presented in Dept. of Physics Undergrad Lecture Series, Purdue University, Jan. 22, 2002.
19. **Microfluidic Diagnostic Techniques**, presented in the Civil Engineering Dept., Purdue University, October 2001.

18. **Experiments and Simulations in Micro/Nano Domains**, Data Storage Institute, Singapore, July 2001.
17. **Experiments and Simulations in Micro/Nano Domains**, Seagate Corp., Singapore, July 2001.
16. **Microfluidic Diagnostic Techniques**, presented in the Mechanical Engineering Dept., Nanyang Technological University, Singapore, July 2001.
15. **Experiments and Simulations in Micro/Nano Domains**, National Storage Industry Consortium Annual Meeting, Monterrey, CA, June 2001.
14. **Fluid Measurements in Micro/Nano Domains**, presented at The Colorado Center for Information Storage/Denver Section of the IEEE Magnetics Society seminar series, Boulder, CO, Jan. 2001.
13. **Microfluidic Diagnostic Techniques**, presented in the Mechanical Engineering Dept., Indiana University and Purdue University at Indianapolis (IUPUI), Indianapolis, IN, Nov. 2000.
12. **Microfluidic Diagnostic Techniques**, presented in the Materials Engineering Dept., Purdue University, West Lafayette, IN, Sept. 2000.
11. **Microfluidic Diagnostic Techniques**, presented at the Purdue University Nanotechnology Seminar Series, Purdue University, West Lafayette, IN, Sept. 2000.
10. **Microfluidics: Theory and Experiment**, presented in the "All-Day MEMS overview," University of Illinois, Chicago, IL, Aug. 2000.
9. **Microfluidic Diagnostic Techniques**, presented at Daimler-Chrysler, Ulm, Germany, July, 2000.
8. **Microfluidic Diagnostic Techniques**, presented at the Paul-Scherrer Institut Laboratory for Micro- and Nanotechnology, Villigen, Switzerland, July, 2000.
7. **Microfluidic Diagnostic Techniques**, presented at 3M, Minneapolis, MN, June, 2000.
6. **MEMS: A brief introduction**, presented in the Monticello Business Forum seminar titled "Technologies of the 21<sup>st</sup> Century and How to Incorporate Them," Monticello, IN, May, 2000.
5. **Fluid Flow in Microscale Domains-Experiments and Analysis**, presented in the Applied Math Seminar Series, Math Department, Purdue University, West Lafayette, IN, Apr. 2000.
4. **Enhanced Micro-PIV**, presented in the Turbulence and Complex Flow Seminar Series, Theoretical and Applied Mechanics Department, University of Illinois, Urbana-Champaign, Feb. 2000.
3. **Microfluidic Diagnostic Techniques**, presented in the Mechanical Engineering Department Lecture Series at the University of Florida, Gainesville, FL, Dec. 1999.
2. **Microfluidic Diagnostic Techniques**, presented in the Society for the Advancement of Material and Process Engineering (SAMPE) Micro-Nano Scale Science and Technology Seminar Series, Purdue University, W. Lafayette, IN, Oct. 1999.
1. **Shear Field and Velocity Field in Taylor Vortex Flow**, presented at Baxter HealthCare, Fenwal Division, Round Lake, IL, Oct. 1996.

## Funding History

**Hummingbird, Inc., Environmental Cells for Transmission Electron Microscopy (TEM)**, Two years (2010-2011), \$225,000.

**NSF:ERC for Compact and Efficient Fluid Power**, Two (2) years (2006-2008), \$5,000,000, \$80,076  
Cummins, Inc.:Proposal for Characterizing Fuel Contaminant Size and Type Two (2) years (2007-2009)  
\$223,666.

**NSF:Experiments and Modeling of Advanced Optical Trap Systems for Manipulating and Sorting Micro and Nano Particles**, Three (3) years (2007-2010), \$212,453

**NSF:Collaborative Research: Architecture and Prototype for a Programmable Lab-on-a-Chip**, Three (3) years (2007-2009), \$315,000, \$142,893

**DARPA: Micro/Nano Fluidics Fundamentals Focus Center (UCI/MF3)**, Three (3) years (2007-2010), \$150,919

**AudioPixels, Inc.:Proposal for micro-PIV measurements to Audiopixels**, One (1) year (2009-2010), \$34,607  
**National Aeronautics and Space Administration (Bionetics Corp./NASA)**, "Microfluidic Ion Sensor Array,"  
2/7/2005 to 9/30/2006, *Total award: \$140k, my portion: \$70k.*

**Air Force Office of Scientific Research**, "STTR: High-resolution evanescent PIV for near-wall microfluidics,"  
9/15/2004 to 6/30/2005, *Total award: \$75k, my portion: \$42k.*

**National Science Foundation**, "Scaling down mechanically driven fluidic self-assembly," 8/15/2004 to  
1/31/2006, *Total award: \$50k.*

**Cooling Technologies Research Center (NSF/Industry consortium)**, "Heat transport in Microchannels,"  
1/1/2004 to 12/31/2006, *Total award: \$115k, my portion: \$57k.*

**Lilly retention initiatives**, "Nanofact/Nanofiction honors class," 1/1/2004 to 5/31/2004, *Total award: \$10k, my portion: \$5k.*



**21<sup>st</sup> Century Research and Technology Fund**—"Novel MEMS-Based Microscale Cooling System for the Thermal Management of Integrated Microelectronics," 2004 to 2006, *Total award: \$1922k, my portion \$39k.*

**National Science Foundation, DMI Materials Processing/Manufacturing**, "GOALI: Improvements spray drying manufacturing through control of drop size distributions," 9/15/2003 to 8/31/2006, *Total award: \$389k, my portion: \$130k.*

**TSI, Inc.**, "PIV algorithm improvements for TSI's Insight," 2003 to 2004, *Total award: \$10k.*

**National Science Foundation, Nanoscale Undergraduate Education**, "NUE: New Learning and Discovery Experiences in Nanoscale Engineering Undergraduate Education," 2003 to 2004, *Total award: \$100k, my portion: \$19k.*

**Purdue Research Foundation**—"Interplay of Randomness and Determinism in Micro/Nanoflows," 2003 to 2005, *Total award: \$13k.*

**National Science Foundation**, "SGER: Development of a multiscale manufacturing teaching laboratory," 2003 to 2004, *Total award: \$100k, my portion: \$17k.*

**National Science Foundation, Nanoscale Science and Engineering, Nanoscale Exploratory Research**—"Explorations in Biomedical Microdevices: Brownian Motion and Education," 2002 to 2003, *Total award: \$100k, my portion \$89k.*

**National Science Foundation, Biological Oceanography**—"Form and Function of Phytoplankton in unsteady, low Reynolds-Number Flows," 9/1/2002 to 8/31/2006, *Total award: \$970k, my portion \$208k.*

**Showalter Trust**, "Towards the prevention and control of atherosclerosis: endothelial and smooth muscle cell response to pulsatile flow in stenotic blood vessels," 2001 to 2002, *Total award: \$83k, my portion: \$16.6k.*

**Naval Surface Warfare Center Crane Division (Purdue University Center for Sensing Science and Technology)**—"Integrated Detection of Hazardous Materials," 2001 to 2003, *Total award: \$4000k, my portion \$70k.*

**21<sup>st</sup> Century Research and Technology Fund**—"Center for Nanoscale Electronics/Biological Devices," 2000 to 2002, *Total award: \$1480k, my portion \$49k.*

**21<sup>st</sup> Century Research and Technology Fund**—"Intelligent MEMS-based Flow Sensors and Controllers," 2000 to 2002, *Total award: \$816k, my portion \$271k.*

**Purdue Research Foundation**—"Experimental Investigation of Prototypical MEMS Pumps," 2000 to 2002, *Total award: \$13k.*

**3M Nontenured Faculty Award**—support for untenured faculty in the pursuit of basic research in the physical and/or biological sciences, 2/24/2000, *Total award: \$39k.*

**ATC, Inc.**, unrestricted gift funding in support of research on micro-scale mass flow transducers, 12/30/1999, *Total award: \$27K.*

### Short Courses

**Principles and Applications of Micro and Nanofluidics**, Center for Smart Interfaces, Darmstadt, Germany; offered twice—Mar 22-24, 2010 and Dec 14-16, 2011.

**Microfluidics**, April 26-28, 2004, Los Angeles, CA. ASME sponsored 3 day short course in which I taught one half day on the theory of flows at small length scales.

**Fundamentals and Applications of Microfluidics**, half day short course offered at ESA's Space Propulsion 2004, Cagliari, Italy, June 2-9, 2004.

**Microfluidics**, April 26-28, 2004, Los Angeles, CA. ASME sponsored 3 day short course in which I taught one half day on the theory of flows at small length scales.

**Fundamentals and Applications of Micro/Nanofluidics**, 3 hour short course offered at *Nanotech 2004*, in Boston, March 7-11, 2004.

**Fundamentals and Applications of Micro/Nanofluidics**, 3 hour short course presented at the *Nanotech 2003*, in San Francisco, Feb. 23-27, 2003. Topics addressed: theoretical background of micro/nano-scale fluid mechanics, modeling methods, practicalities of small-scale flows, experimental characterization techniques.

**Microfluidics**, half-day short course presented at the *International MEMS Workshop 2001*, in Singapore, July 4-6, 2001. Co-taught with Dr. Nam-Trung Nguyen, Nanyang Technical University, Singapore. Topics addressed: theoretical background of micro-scale fluid mechanics, experimental characterization techniques for microflows, fabrication technologies of microfluidic devices, and typical microfluidic applications.

### Awards and Memberships

**2<sup>nd</sup> Place, Gold Division, Burton D. Morgan Business Plan Competition**, company name PathVis, now OmniVis, 2017.

**Purdue Innovator Hall of Fame inductee** (2016)

**United States Geological Survey Director's Award** for meritorious service to the nation during the Deepwater Horizon oil spill (2010).

**3<sup>rd</sup> Prize, ASME-IMECE Society-Wide Micro/Nano Technology Forum Best Poster Competition**, HS Chuang, A Kumar, and ST Wereley, "Rapid Electrokinetic Patterning Of Colloidal Particles With Optical Landscapes", Lake Buena Vista, Florida, 2009

**Alexander von Humboldt Fellow** (3/2007-8/2007; 6/2008-7/2008; 6/2009-7/2009)

**1st Place, Gold Division**, Burton D. Morgan Business Plan Competition. Ahmed M. Amin, S.C. Jacobson, M. Thottethodi, T.N. Vijaykumar and S.T. Wereley. "Microfluidic Innovations." Purdue University, West Lafayette, IN, February 2009.

**2nd Place, Gold Division**, Burton D. Morgan Business Plan Competition. SJ Williams, H.-S. Chuang and A Kumar. Liquid Qinetics. Purdue University, West Lafayette, IN, Feb. 24, 2009.

**1st Place Poster, Engineering Sciences**, SJ Williams, A Kumar, and ST Wereley, "Rapid electrokinetic patterning of colloids using optical landscapes", 2009 Graduate Student Poster Competition sponsored by Sigma Xi, Purdue University, West Lafayette, IN, Feb. 2009.

**3rd Place, 2008 Ecological Science and Engineering Poster Competition**. H.-S. Chuang and Steven T. Wereley. "Open Optoelectrowetting Droplet Actuation for Lab-on-a-Chip Applications." Dec. 5, 2008.

**Outstanding Video**, Gallery of Fluid Motion at Amer. Phys. Soc./Div. Fluid Dyn. Annual Meeting, SJ Williams, A Kumar, and ST Wereley, "Optically induced electrokinetic patterning and manipulation of particles," San Antonio, TX, Nov. 2008. *Note*: Most downloaded video from eCommons@Cornell for the month of December, 2008. (<http://hdl.handle.net/1813/11399>)

**"2008 Highlight"** distinction conferred by the journal Measurement Science and Technology to the article "Three-dimensional particle tracking using micro-particle image velocimetry hardware" by Peterson, Chuang, and Wereley.

**Young Researcher Poster Award Winner** at Proc. 12th International Conference on Miniaturized Systems for Chemistry and Life Sciences ( $\mu$ TAS 2008), A Kumar, SJ Williams and ST Wereley, "Rapid electrokinetic patterning of colloids using optical landscapes", San Diego, USA, Oct 12-16, 2008.

**Best Poster Award** at the 2nd Annual Birck Nanotechnology Research Review, S. Williams, A. Kumar, and S.T. Wereley, "Rapid electrokinetic patterning of colloidal particles with optical landscapes," April 14, 2008.

**21st Annual Purdue University Burton Morgan Business Plan Competition**, 4<sup>th</sup> place, A. Amin, H.S. Chuang, T.N. Vijaykumar, T. Thodentoddi, S.T. Wereley, and S. Jacobson, developed a business plan for commercializing programmable Lab-on-a-Chip devices.

**Seeds for Success Award (1/2007)**—awarded for proposals funded in excess of one million dollars

**3M Nontenured Faculty Award (3/2000, 3/2001, 3/2002)**—support for untenured faculty in the pursuit of basic research in the physical and/or biological sciences.

**Walter Murphy Fellowship (9/1990)**—support for outstanding graduate students

**Pi Tau Sigma Mechanical Engineering Honor Society**: student member (4/89); faculty advisor (4/99-present)

**American Physical Society (APS)**

**American Society of Mechanical Engineers (ASME)**

**American Institute of Aeronautics and Astronautics (AIAA)**

## Guest Class Lectures

**Microscale Heat and Fluid Flow Diagnostics**, ME 605, *Convection of Heat and Mass*, Professor Jayathi Murthy, Dec. 2003.

**Fundamentals of Microfluidics**, EE 595B, *Fundamentals of MEMS and Micro-Integrated Systems*, Professor Rashid Bashir, Oct., 2003.

**An Introduction to Nanotechnology**, ENGL373, *Science Fiction and Fantasy*, Prof. Kristina Bross, Feb. 2003.

**Fundamentals of Microfluidics**, EE 595B, *Fundamentals of MEMS and Micro-Integrated Systems*, Professor Rashid Bashir, Oct., 2002.

**The Benefits of a Physics Education in Mechanical Engineering**, PHYS 290A, *Seminar in Careers in Physics*, Professor Andrew Hirsch, Jan. 2002.

**Microscale Heat and Fluid Flow Diagnostics**, ME 605, *Convection of Heat and Mass*, Professor Suresh Garimella, Apr. 2001.

**Fundamentals of Microfluidics**, EE 595B, *Fundamentals of MEMS and Micro-Integrated Systems*, Professor Rashid Bashir, Feb., 2001.

**Microscale Fluid Flow Diagnostics**, ME 509, *Intermediate Fluid Dynamics*, Professor Steve Frankel, Dec. 2000.

**Microscale Fluidic Actuation**, ME 610, *Boundary Layer Theory*, Professor Mike Plesniak, Apr., 2000.

**Microscale Pumping Schemes**, EE 595B, *Fundamentals of MEMS and Micro-Integrated Systems*, Professor Rashid Bashir, Apr., 2000.

**Math and Science in Tom Stoppard's Arcadia**, ENGL 201, *The Nature of Literary Study*, Professor Kristina Bross, Apr., 2000.

**Fundamentals of Microfluidics**, EE 595B, *Fundamentals of MEMS and Micro-Integrated Systems*, Professor Rashid Bashir, Feb., 2000.

**Some thoughts on the science in Tom Stoppard's Arcadia**, THTR 570, *Dramatic Structure and Literature*, Professor Anne Fliotsos, Feb., 2000.

**Microscale Fluid Flow Diagnostics**, ME 509, *Intermediate Fluid Dynamics*, Professor Carl Wassgren, Dec. 1999.

### **Conference Sessions Chaired *current through 2002***

**Biomedical Flows**: 11<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal), July 8-11, 2002.

**Challenges in Micro and Nanoscale Transport**: THERMES 2002: Thermal Challenges in Next Generation Electronic Systems, (Santa Fe, NM), January 13-16, 2002.

**BioMEMS & Microfluidic & MEMS/MST Sensor Applications**: International MEMS Workshop, (Singapore), July 4-6, 2001.

**Micro-Fluid Dynamics II**: American Physical Society/Division of Fluid Dynamics Annual Meeting, (Washington, D.C.), Nov.19-21, 2000.

**Aerodynamic Flows – 2**: 10<sup>th</sup> International Symposium on the Application of Laser Techniques to Fluid Mechanics, (Lisbon, Portugal), July 10-13, 2000.

**Interrogation Algorithms**, The Third International Workshop on Particle Image Velocimetry (Santa Barbara, CA), Sept. 12-14, 1999.

### **Journal Reviews**

AIAA Journal, AIChE Journal, J. Fluids Engineering, J. Micromechanics and Microengineering, Physics of Fluids, Experiments in Fluids, J. Fluid Mechanics, ...

### **Courses Taught**

**ME697W: Micro/Nano Fluid Mechanics**: Fa05, Fa08

**ENGR195N: Special Topics in Nanotechnology Research Experiences**: Sp04 (team taught with Freshman Eng.)

**HONR199C: Nanofact/Nanofiction**: Sp04 (co-taught with K. Bross, ENGL)

**ME263: Introduction to Mechanical Engineering Design**: Sp01

**ME309: Introduction to Fluid Mechanics**: Fa99, Sp00 (Lead), Fa00, Fa04 (2 sections)

**ME509: Intermediate Fluid Mechanics**: Fa01, Fa02, Fa06

**ME595W: Fundamentals of Particle Image Velocimetry**: Sp02, Sp05

**ME/ChE517: Micro/Nanoscale Physical Processes**: Sp01\*, Sp02\*, Sp03\*, Sp04\*, Sp06, Sp08\*, Sp09

**ME610: Theory of Boundary Layer Flows**: Fa03

\*co-taught with Gil Lee, CHE

### **School/College/University Service**

**Fluid Mechanics Area Chair** (5/2008-Present)

**ME Leadership Team** (5/2008-Present)

**Fluid Mechanics Seminar Series Organizer** (1/2000-5/2006)

**Faculty Advisor to Pi Tau Sigma**, the Mechanical Engineering Honor Society (4/2000-Present)

**College of Engineering Academic Grievance Committee** (8/2000-5/2004)

**ME Head's Advisory Council** (8/2003-5/2006)

**ME Research Committee** (8/2001-8/2003)

**Heat Transfer Faculty Search Committee** (8/2001-5/2002)

**Computational Thermal Sciences Faculty Search Committee** (12/2000-7/2001)

**Laboratory Committee** (3/2001-8/2001)

**Graduate Committee** (8/1999-8/2001)

# **EXHIBIT 1**

**FILED UNDER SEAL**















# **EXHIBIT 2**

**FILED UNDER SEAL**

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Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

GE HEALTHCARE BIO-SCIENCES AB,  
and GLOBAL LIFE SCIENCES  
SOLUTIONS USA, LLC,

Plaintiffs,

v.

BIO-RAD LABORATORIES, INC.

C.A. No. 18-

1899-CFC

CONSOLIDATED

Defendant.

\_\_\_\_\_)

HIGHLY CONFIDENTIAL -- ATTORNEYS' EYES ONLY  
CONFIDENTIAL BUSINESS INFORMATION  
DEPOSITION OF ROBERT IOVANNI  
APPEARING REMOTELY

June 11, 2020

9:02 a.m. Pacific

Reported by: Lori J. Goodin, RPR, CLR, CRR,  
RSA, California CSR #13959

\_\_\_\_\_  
DIGITAL EVIDENCE GROUP  
1730 M Street, NW, Suite 812  
Washington, D.C. 20036  
(202) 232-0646



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1 REMOTE APPEARANCES:

2 FOR GE HEALTHCARE BIO-SCIENCES AB:

3 JEFFREY A. MILLER, ESQUIRE

JOSEPH PALMIERI, ESQUIRE

4 ARNOLD & PORTER KAYE SCHOLER LLP

300 El Camino Real

5 Five Palo Alto Squire

Suite 500

6 Palo Alto, California 94306

415-356-3000

7 jeffrey.miller@arnoldporter.com

8

9 FOR BIO-RAD LABORATORIES:

10 FELIPE CORREDOR, ESQUIRE

QUINN EMANUEL URQUHART & SULLIVAN, LLP

11 50 California Street

22nd Floor

12 San Francisco, CA 94111

415-875-6448

13 felipecorredor@quinnemanuel.com

14

15 AND COCOUNSEL:

JOHN CASSINGHAM, ESQUIRE

16 BIO-RAD LABORATORIES, INC.

2754 Compass Drive

17 Suite 300

Grand Junction, Colorado 81506

18 510-724-7000

19

20 ALSO PRESENT:

21 Glen Fortner, videographer

22 James Beall, document technician

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1 INDEX TO EXAMINATION

2 WITNESS: ROBERT IOVANNI

3 PAGE

4 EXAMINATION BY MR. MILLER 9

5 MR. CORREDOR 300

6 MR. MILLER 302

7

8 \* \* \*

9 INDEX TO EXHIBITS

10 ROBERT IOVANNI

11 Thursday, June 11, 2020

12 Lori J. Goodin, RPR, CLR, CRR,

13 RSA, California CSR #13959

14

15 MARKED DESCRIPTION PAGE

16 Exhibit 1 Notice of Deposition 15

17 Exhibit 2 30(b)(6) notice 15

18 Exhibit 3 [REDACTED] [REDACTED]

[REDACTED] BRGE0006279-6341

19 Exhibit 4 [REDACTED] [REDACTED]

[REDACTED] BRGEDEL288592-288623

20 Exhibit 5 Presentation for Product 106

Proposal meeting, BRGE65053-65075

21 Exhibit 6 [REDACTED] [REDACTED]

[REDACTED], BRGE6302-6305

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1	MARKED	DESCRIPTION
2		PAGE
3	Exhibit 7	[REDACTED]
		[REDACTED]
		[REDACTED] BRGE65076
5	Exhibit 8	[REDACTED]
		[REDACTED] BRGE6351-6366
6	Exhibit 9	[REDACTED] 131
		BRGE6227
7	Exhibit 10	[REDACTED] 136
		BRGE6470-6479
8	Exhibit 11	[REDACTED] 159
9		BRGEDEL610165
10	Exhibit 12	Block diagram for presentation 163
		BRGEDEL610166
11	Exhibit 13	Basic fluidic diagram 163
		BRGEDEL610217
12	Exhibit 14	Fluidic diagram 165
		BRGEDEL610216
13	Exhibit 15	Fluidic diagram 166
		BRGEDEL610218
14	Exhibit 16	[REDACTED]
		[REDACTED] BRGE65080
15	Exhibit 17	Early Industrial Design, View 1 182
		BRGEDEL21985
16	Exhibit 18	Early Industrial Design, View 2 183
		BRGEDEL22056
17	Exhibit 19	Early Industrial Design, View 3 183
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18	Exhibit 20	Early Industrial Design, View 4 183
19		BRGEDEL22768
20	Exhibit 21	Early Industrial Design, View 5 183
21		BRGEDEL22853
22		

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1	EXHIBITS CONTINUED		
2	MARKED	DESCRIPTION	PAGE
3	Exhibit 22	Early Industrial Design, View 6 BRGEDEL22913	183
4	Exhibit 23	Diagram with notes BRGEDEL23006	184
5	Exhibit 24	Fluidic Diagram with steps BRGEDEL23066	184
6	Exhibit 25	[REDACTED] [REDACTED], BRGEDEL341332-341334	
7	Exhibit 26	[REDACTED] BRGEDEL341373-74	195
8	Exhibit 27	[REDACTED] BRGE16955-16987	196
9	Exhibit 28	[REDACTED] BRGEDEL610167	211
10	Exhibit 29	[REDACTED] [REDACTED]	
11		BRGEDEL401625-401658	
12	Exhibit 30	[REDACTED] [REDACTED], BRGEDEL14644-14657	
13	Exhibit 31	[REDACTED] BRGEDEL401312-401330	218
14	Exhibit 32	U.S. Patent 8,821,718	223
15	Exhibit 33	[REDACTED] [REDACTED], BRGE34403	
16	Exhibit 34	Quote from GE to Bio-Rad for sale of Avant, 9/23/2009 BRGEDEL175227-175228	241
17			
18	Exhibit 35	E-mail from Mavandadi 9/30/2009, BRGEDEL300620	242
19			
20	Exhibit 36	Attachment to Exhibit 35 e-mail BRGEDEL300621-300645	242
21			
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1	EXHIBITS CONTINUED		
2	MARKED	DESCRIPTION	PAGE
3	Exhibit 37	E-mail from S. Lin, 4/8/2010 BRGE421000	250
4	Exhibit 38	[REDACTED] [REDACTED] BRGEDEL217218-217219	[REDACTED]
5			
6	Exhibit 39	E-mail, Avant service repair report, 5/17/2011 BRGEDEL393786-393789	256
7			
8	Exhibit 40	[REDACTED] [REDACTED], BRGEDEL201040-201041	[REDACTED]
9	Exhibit 41	[REDACTED] [REDACTED], BRGEDEL335768	[REDACTED]
10	Exhibit 42	E-mail, Urban, attached to Pleadings, 10/26/2012 3538474_1	277
11			
12	Exhibit 43	Hardware Specification for NGC BRGEDEL0044322-445336	286
13	Exhibit 44	US Patent 10,401,335	294

(All exhibits were provided.  
electronically to the reporter.)

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1 REPORTED REMOTELY FROM WASHINGTON, D.C.

2 THURSDAY, JUNE 11, 2020, 9:00 a.m.

3 \* \* \*

4

5 PROCEEDINGS

6 THE VIDEOGRAPHER: This is Tape  
7 Number 1 of the videotaped deposition of  
8 Robert Iovanni taken by counsel for the  
9 plaintiff In the Matter of GE Healthcare  
10 Bio-Sciences AB, et al. v. Bio-Rad  
11 Laboratories, Inc., in the United States  
12 District Court for the District of Delaware.  
13 Case Number 18-1899 CFC.

14 This deposition is being conducted  
15 on Zoom and being recorded at Tyson's Corner  
16 Virginia, on June 11, 2020.

17 The time on the video screen is 9:02  
18 Pacific time.

19 My name is Glen Fortner. I am the  
20 legal videographer, from Digital Evidence  
21 Group.

22 The court reporter is Lori Goodin,

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1 in association with Digital Evidence Group.

2 Will counsel please introduce  
3 themselves for the record.

4 MR. MILLER: My name is Jeffrey  
5 Miller from Arnold & Porter. And with me is  
6 Joseph Palmieri, also from Arnold and Porter.

7 MR. CORREDOR: Good morning, Felipe  
8 Corredor from Quinn Emanuel on behalf of  
9 Bio-Rad, and with me is John Cassingham from  
10 Bio-Rad.

11 THE VIDEOGRAPHER: Will the court  
12 reporter please swear in the witness.

13 THE REPORTER: Counsel, before  
14 swearing in the witness, I have a short  
15 statement to put on the record.

16 The attorneys participating in this  
17 deposition acknowledge that due to the  
18 severity of COVID-19 and following the  
19 practice of social distancing, I am not  
20 physically [resent in the deposition room and  
21 that I will be swearing in the witness and  
22 reporting this deposition remotely.

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1 All parties stipulate to the  
2 validity of this remote swearing and remote  
3 reporting via video conference and that it  
4 will be admissible in the courtroom as if it  
5 had been taken following Rule 30 and other  
6 rules of the Federal Rules of Civil Procedure.

7 \* \* \*

8 ROBERT IOVANNI

9 THE REPORTER: Do you solemnly state  
10 that the testimony you are about to give in  
11 the cause now pending will be the truth, the  
12 whole truth, and nothing but the truth, so  
13 help you God.

14 THE WITNESS: I do.

15 \* \* \*

16 EXAMINATION

17 BY MR. MILLER:

18 Q. Good morning. Can you please state  
19 your full name for the record.

20 A. Sure. Robert Alan Iovanni.

21 Q. We will get into your education in a  
22 little bit, but do you have a Ph.D. or no?



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1 initials PP. Do you have an understanding as to  
2 what PP stands for?

3 A. Protein purification.

4 Q. And in the portion there you see, it  
5 says, [REDACTED]

■ [REDACTED]

■ [REDACTED]

8 Do you see that?

9 A. Yes.

10 Q. You mentioned earlier that the  
11 DuoFlow was an existing product for Bio-Rad when  
12 you came into this portion of Bio-Rad.

13 Do you remember that?

14 A. Yes.

15 Q. In 2008, did you have an  
16 understanding as to [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

7 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

17 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

21 Q. If we could go to the BRGE 6284 of

22 the document. And then towards the bottom third

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1 of the page there is a section entitled [REDACTED]

■

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9 Do you see that?

10 A. Yes.

11 MR. CORREDOR: Objection to the  
12 form.

13 BY MR. MILLER:

14 Q. Was the DuoFlow system that Bio-Rad  
15 had on the market at the time, was it a modular  
16 system?

17 A. Yes.

18 Q. And what was it about the DuoFlow  
19 system that made it modular?

20 A. We offered different types of  
21 components that the user could use depending on  
22 what type of chromatography they were looking to

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1 Page 14 of the document, Exhibit 4.

2

[REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED] [REDACTED]

■ [REDACTED] [REDACTED]

■ [REDACTED] [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

13 Do you see that?

14 A. Yes.

15 Q. Do you know what the ÄKTA purifier  
16 was?

17 A. It was one of the competitive  
18 machines.

19 Q. And that was from GE, right?

20 A. Yes.

21 Q. [REDACTED]

■ [REDACTED]

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1 MR. MILLER: Why don't we mark as  
2 the next exhibit and get it to the Share  
3 folder, the Bates Number bearing BRGE65053  
4 through BRGE65075.

5 (Exhibit Number 5  
6 marked for identification.)

7 BY MR. MILLER:

8 Q. Let me ask you a quick question  
9 about the previous document?

10 A. Uh-huh.

11 Q. Is that a document that you reviewed  
12 in preparation for your deposition today?

13 A. Yes.

14 Q. All right. Let's move to the next  
15 exhibit which I believe is Exhibit 5 which we  
16 have just marked.

17 Can you take a look at it and tell  
18 me if you can identify it?

19 A. It looks like the presentation for  
20 the day of that meeting.

21 Q. If I ever meet Ms. Mavandadi I have  
22 to apologize because it appears she has a Ph.D.?

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1 page.

2 MR. MILLER: Okay.

3 THE WITNESS: There we go.

4 BY MR. MILLER:

5 Q. Okay. [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

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[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

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1 MR. CORREDOR: Objection.

2 Mischaracterizes the document.

3 MR. MILLER: I'm not trying to  
4 mischaracterize anything. So, make sure that  
5 I'm not mischaracterizing, Mr. Iovanni.

6 THE WITNESS: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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1 BY MR. MILLER:

2 Q. In the NGC system that was  
3 eventually released, were users able to easily  
4 add, replace or reposition the modules?

5 MR. CORREDOR: Objection, form.

6 THE WITNESS: Yes. I think  
7 relatively speaking, yes.

8 BY MR. MILLER:

9 Q. And why would users want to add a  
10 module?

11 MR. CORREDOR: Objection, calls for  
12 speculation.

13 BY MR. MILLER:

14 Q. Let me ask you this: Do you know  
15 why users would add modules to their NGC systems  
16 as they were eventually sold?

17 A. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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MR. CORREDOR: Objection, vague.

9

MR. MILLER: Let's mark as

10

Exhibit 29 a document bearing the Bates

11

Number BRGEDEL401625 through BRGE 401658.

12

(Exhibit Number 29

13

marked for identification.)

14

BY MR. MILLER:

15

Q. Once that shows up, if you can

16

identify Exhibit 29 for us.

17

A. So, this is 29. Okay.

18

Q. Can you identify Exhibit 29 for us,

19

please?

20

A. It is a technical specification for

21

the system.

22

Q. █

1



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MR. MILLER: Mark the next exhibit

bearing the Bates number BRGEDEL14644 through  
14657.

(Exhibit Number 30

marked for identification.)

BY MR. MILLER:

Q. When it is in the Share if you can  
identify that document, that would be great.

A. This will be Number 30?

Q. Yes, Exhibit 30. I will give you a  
chance to review Exhibit 30.

A. It hasn't come in yet. Here it is.  
All right. Okay.

Q. Can you identify Exhibit 30 for us,  
please?

A.



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1 CERTIFICATE OF COURT REPORTER

2 UNITED STATES OF AMERICA )

3 DISTRICT OF COLUMBIA )

4 I, LORI J. GOODIN, a Certified Shorthand  
Reporter do hereby certify:

5 That prior to being examined, the witness  
in the foregoing proceedings was by me duly sworn  
6 to testify to the truth, the whole truth, and  
nothing but the truth.

7 That said proceedings were taken remotely  
before me at the time and places therein set  
8 forth and were taken down by me in shorthand and  
thereafter transcribed into typewriting under my  
9 direction and supervision;

10 I further certify that I am neither  
counsel for, nor related to, any party to said  
11 proceedings, not in any wise interested in the  
outcome thereof.

12 In witness whereof, I have hereunto  
subscribed my name.

13 Dated: June 11, 2020

14

15

16

17

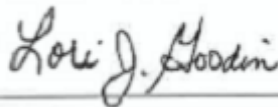
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19

20

21 My Commission expires: May 14, 2021

22



Lori J. Goodin, RPR, CLR, CRR,  
RSA, California CSR #13959

# **EXHIBIT 3**

**FILED UNDER SEAL**

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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB, et al., )  
 )  
 Plaintiff, )  
 v. ) Case No. 1:18-CV-  
 ) 01899-CFC  
 BIO-RAD LABORATORIES, )  
 INCORPORATED, )  
 )  
 Defendants. )  
 \_\_\_\_\_ )

HIGHLY CONFIDENTIAL TECHNICAL ATTORNEYS EYES ONLY  
PURSUANT TO PROTECTIVE ORDER

DEPOSITION OF PHILIP CHAPMAN, MSc  
30(b)6 and Personal Capacity, Volume II

APPEARING REMOTELY

July 24, 2020  
12:11 P.M.

Reported by: Lori J. Goodin, RPR, CLR, CRR,  
RSA, California CSR #13959

\_\_\_\_\_  
DIGITAL EVIDENCE GROUP  
1730 M Street, NW, Suite 812  
Washington, D.C. 20036  
(202) 232-0646

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REMOTE APPEARANCES:

3

4

FOR PLAINTIFF:

ARNOLD & PORTER KAYE SCHOLER LLP

5

JEFFREY A. MILLER, ESQUIRE

3000 El Camino Real Five Palo Alto

6

Square, Suite 500

Palo Alto, CA 94306-3807

7

650.319.4538

8

Jeffrey.Miller@arnoldporter.com

9

10

FOR DEFENDANT:

QUINN EMANUEL URQUHART & SULLIVAN, LLP

11

FELIPE CORREDOR, ESQUIRE

50 California Street

12

22nd Floor

San Francisco, California 94111

13

415-875-6600

14

Felipecorredor@quinnemanuel.com

15

16

ALSO PRESENT:

17

Sarah Howard, videographer

18

James Beall, document technician

19

20

21

22

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2 WITNESS: PHILIP CHAPMAN, MSc

3

4 EXAMINATION BY PAGE

5 MR. MILLER 319

6

7 \* \* \*

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11 Cytiva Sweden, AB, et al., v. Bio-Rad

12 Laboratories, Incorporated

13 Friday, July 24, 2020

14 Lori J. Goodin, RPR, CLR, CRR,

15 RSA, California CSR #13959

16 MARKED DESCRIPTION PAGE

17 Exhibit 209 Philip Chapman 30(b)(6) Topics 320

18 Exhibit 210 Plaintiffs' Amended Notice of  
19 Deposition of Philip Chapman 330

20 Exhibit 211 NGC Chromatography System and  
ChromLab Software Instrument  
21 Guide 332

22

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7	RSA, California CSR #13959		
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9	Exhibit 212	NGC Chromatography Systems and	
10		ChromLab Software Installation	
11		Guide	333
12	Exhibit 213	NGC Chromatography Systems and	
		ChromLab Software User Guide	335
13	Exhibit 214	NGC Chromatography Systems and	
		ChromLab Software Installation	
14		Guide	336
	Exhibit 215	NGC Chromatography Systems	
15		Multidimensional Plumbing Guide	429
16	Exhibit 216	[REDACTED]	
		[REDACTED]	499
17	Exhibit 217	[REDACTED]	
		[REDACTED]	540
18	Exhibit 218	[REDACTED]	
		[REDACTED]	545
19	Exhibit 219	[REDACTED]	
		[REDACTED]	
20	[REDACTED]	[REDACTED]	548
21	Exhibit 220	[REDACTED]	
		[REDACTED]	
22	[REDACTED]	[REDACTED]	550

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7	RSA, California CSR #13959		
8	MARKED	DESCRIPTION	PAGE
9	Exhibit 221	[REDACTED]	
10	[REDACTED]	[REDACTED]	552
11	Exhibit 222	[REDACTED]	
12	[REDACTED]	[REDACTED]	553
13	Exhibit 223	[REDACTED]	
14	[REDACTED]	[REDACTED]	555
15	Exhibit 224	[REDACTED]	
16	[REDACTED]	[REDACTED]	605
16	Exhibit 225	Moran e-mail, 5/21/10	614
17	Exhibit 226	attachment to Exhibit 225	615
18	Exhibit 227	attachment to Exhibit 225	615
19	Exhibit 228	attachment to Exhibit 225	615
20	Exhibit 229	attachment to Exhibit 225	615
21	Exhibit 230	attachment to Exhibit 225	615
22	Exhibit 231	attachment to Exhibit 225	615

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8

MARKED

DESCRIPTION

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Exhibit 232 e-mail chain, 9/30/13

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Exhibit 233 PowerPoint, 10/9/15

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11

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Exhibit 234

[REDACTED]

13

[REDACTED]

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14

Exhibit 235 Brown and Bilsker e-mail

15

exchange, 10/17/14

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Exhibit 236 Brown and Bilsker e-mail

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exchange, 3/16/15

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Exhibit 237 summary of topics for Philip

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Chapman 30 (b) (6)

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RSA, California CSR #13959

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PRIOR MARKED EXHIBITS

FIRST REFERRAL

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Lori J. Goodin, RPR, CLR, CRR,

RSA, California CSR #13959

PREVIOUSLY MARKED EXHIBITS

PRIOR MARKED EXHIBITS	FIRST REFERRAL
63	560
64	561
83	626
113	608
114	608
185	485

\* \* \*

(All exhibits were provided  
electronically to the court reporter.)

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1 FRIDAY, JULY 24, 2020, 12:11 P.M.

2 PROCEEDINGS

3 \* \* \*

4 THE VIDEOGRAPHER: This is Volume II  
5 of the videotaped deposition of Dr. Philip  
6 Chapman in the matter of Cytiva Sweden AB,  
7 et al. versus Bio-Rad Laboratories,  
8 Incorporated, in the United States District  
9 Court for the District of Delaware, Case  
10 Number 1:18-cv-01899-CFC.

11 This deposition is being held remote  
12 by Zoom video conference physical reporting  
13 on July 24, 2020. The time on the video  
14 screen is 12:11 p.m.

15 My name is Sarah Howard. I am the  
16 legal videographer for Digital Evidence  
17 Group. The court reporter today is Lori  
18 Goodin in association with Digital Evidence  
19 Group.

20 All parties to this deposition are  
21 appearing remotely and have agreed to have  
22 the witness sworn in remotely. Due to the

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1 nature of remote reporting, please pause  
2 briefly before speaking to ensure all parties  
3 are heard completely.

4 Counsel will be identified on the  
5 stenographic record for appearances. The  
6 witness has been previously sworn in, so  
7 please proceed.

8 \* \* \*

9 PHILIP CHAPMAN, MSc,  
10 a witness called for continued examination,  
11 having been previously duly sworn, was examined  
12 and testified further as follows:

13 \* \* \*

14 EXAMINATION

15 BY MR. MILLER:

16 Q. Good morning, Mr. Chapman. My name  
17 is Jeffrey Miller. I will be taking the second  
18 day of your deposition. And I understand that  
19 you went yesterday, so you probably know the  
20 rules of the road; is that correct?

21 A. Yes, correct.

22 Q. And you understand that the oath you

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1 valve. Correct?

2 A. That's correct.

3 Q. What is the purpose of a sample  
4 inject valve in the NGC system?

5 MR. CORREDOR: Object to form.

6 THE WITNESS: So, the purpose of an  
7 inject valve in any liquid chromatography  
8 system is to enable the scientist to inject  
9 their biological sample of interest, to have  
10 it then be introduced onto the chromatography  
11 column.

12 BY MR. MILLER:

13 Q. And the sample inject valve is  
14 included on all versions of the NGC. Correct?

15 A. Yes.

16 Q. So, there are various portions of  
17 the sample inject valve that are shown in an  
18 exploded view on Page 37. Do you see that?

19 A. I do, yes.

20 Q. So, first, we have -- let's try to  
21 get some terminology consistent here.

22 First, there is the big rectangle

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1 that incorporates the circular portion. Do you  
2 see that?

3 A. Yes.

4 Q. Does Bio-Rad have a naming  
5 convention for that rectangular item?

6 A. It is called the face plate or the  
7 overlay, interchangeably.

8 It is actually the overlay. It is  
9 the colored portion.

10 Q. So, I see that there is sort of a --  
11 there is the colored portion -- let me start  
12 again.

13 Is the colored portion that we see  
14 on Page 37 of the instrument guide, is that the  
15 overlay?

16 A. Yes.

17 Q. And, it appears to be incorporated  
18 by some other portion of the module.

19 Do you see that?

20 A. The surrounding part, that is the  
21 face plate. That is the front metal panel to the  
22 housing.

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1 Q. And do all of the modules that  
2 Bio-Rad makes available with the NGC system  
3 include a face plate and an overlay?

4 A. Yes.

[illegible]

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BY MR. MILLER:

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Q.

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1 MR. CORREDOR: Object to the form.

2 THE WITNESS: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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(Whereupon, previously marked

Exhibit 46, first referral.)

BY MR. MILLER:

Q. I have a few brief questions for you  
of a document that has previously been marked as

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1 Exhibit 46.

2 When that gets into the share, let  
3 us know.

4 A. I will, thank you. Exhibit 46?  
5 Correct?

6 Q. Yes.

7 A. Okay, I'm looking at that now.  
8 Okay. I have that in front of me now.

9 Q. Have you ever seen this document  
10 before?

11 A. I wasn't listed as a signatory on  
12 it, but I quite probably have seen it or the  
13 information contained within.

14 Q. So, can you identify Exhibit 46 for  
15 us, please.

16 A. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

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1 Bates number BRGEDEL 450747.

2 A. Okay.

3 Q. And I'm sorry. I read the wrong  
4 number.

5 BRGEDEL 450746, the previous page.

6 A. 746. Okay.

7 Q. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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Q. If you could go to BRGEDEL 450753,  
please, of Exhibit 56. Are you there?

A. Sorry, I closed it. I need to  
reopen it quickly. And it was Exhibit 56, you  
said?

Q. Yes.

Do you see that?

A. One moment, please. Sorry.

Juggling between screens.

Which page did you say it was? Can  
you give me that stamp again?

Q. 450753.

A. 753, yes. Thank you.

Q. And we are looking at Row D, or the  
D row.

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Q. Was this specification met for the inject valve module that Bio-Rad sells with its NGC system?

MR. CORREDOR: Object to the form.

THE WITNESS: My opinion would be yes.

BY MR. MILLER:

Q. Is the same thing true for the pump modules?

MR. CORREDOR: Object to the form.

THE WITNESS: I -- we would need to go and see if that was listed as a requirement and --

BY MR. MILLER:

Q. Sure, let's go to Exhibit 47, please. And let's go to BRGE 96090.

[REDACTED]

[REDACTED]

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Do you see that?

7

A. I do see that.

8

Q. Was this specification met by the

9

pump -- NGC pump module sold with the NGC system?

10

A.

11

, I would say yes.

12

Q.

13

14

15

MR. CORREDOR: Object to the form.

16

THE WITNESS: For the pump, yes, I

17

would say yes.

18

BY MR. MILLER:

19

Q. Thank you. Let's go to Exhibit 50.

20

Exhibit 50 you may recall is the specification

21

for the column switching valve.

22

A. Yes.



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1 Q. And if we could go to  
2 BRGEDEL 450606.

3 A. 606. Okay.

4 Q. Again, the specification for the NGC  
5 column switching valve module states, [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

11 Do you see that?

12 A. I do see that, yes.

13 Q. Was this specification met by the  
14 column switching valve module that Bio-Rad sells  
15 for its NGC system?

16 MR. CORREDOR: Object to the form.

17 THE WITNESS: [REDACTED]

■ [REDACTED] yes.

19 BY MR. MILLER:

20 Q. [REDACTED]

■ [REDACTED] That

22 specification was met as well, correct?

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1 MR. CORREDOR: Object to the form.

2 THE WITNESS: For the column

3 switching valve, yes.

4 BY MR. MILLER:

5 Q. Pull up Exhibit 52, please.

6 [REDACTED]

7 [REDACTED]

8 A. Correct.

9 Q. If you could go to BRGEDEL 282561.

10 A. 561, yes.

11 Q. I'm sorry. I keep doing this to  
12 you.

13 560.

14 A. 560, okay.

15 Q. And the specification here for the  
16 single-wavelength detector module states, [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 Do you see that?

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1 A. I do see that, yes.

2 Q. And, are was this specification met  
3 for the single-wavelength detector module for the  
4 NGC system?

5 MR. CORREDOR: Object to the form.

6 THE WITNESS: [REDACTED]

7 [REDACTED] yes.

8 BY MR. MILLER:

9 Q. [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 MR. CORREDOR: Object to the form.

13 THE WITNESS: For the detector, yes.

14 BY MR. MILLER:

15 Q. Let's pull up Exhibit 54, please.

16 Exhibit 54, as you might remember, is the

17 [REDACTED]

18 [REDACTED] right?

19 A. Correct.

20 Q. If we could go to the page with the  
21 Bates number BRGEDEL 281538.

22 A. 1538, yes.

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1 Q. We have the same specification here  
2 which states the design -- this is in Item D.

3 A. Yes. I'm looking at it, yes.

4 Q. It states, the specification states,

5 [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

10 Do you see that?

11 A. Yes.

12 Q. Does the multi-wavelength detector  
13 module that Bio-Rad sells for its NGC system meet  
14 this specification?

15 MR. CORREDOR: Object to the form.

16 THE WITNESS: [REDACTED]

[REDACTED] yes.

18 (Whereupon, previously marked  
19 Exhibit 57, first referral.)

20 BY MR. MILLER:

21 Q. Can we provide the witness with  
22 Exhibit 57.

7/24/2020

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1 A. I have Exhibit 57 in front of me.

2 Q. Thank you. Can you identify  
3 Exhibit 57 for us, please.

4 A. So, according to the title on the  
5 first page, this is the [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

15 (Whereupon, previously marked  
16 Exhibit 58, first referral.)

17 MR. MILLER: Why don't we provide  
18 the witness with what has been marked as  
19 Exhibit 58, previously.

20 THE WITNESS: May I close 57 or will  
21 we go back to that one?

22 BY MR. MILLER:

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1           A.     I will. Okay, thank you. I'm  
2 looking at the document now.

3           Q.     Can you identify Exhibit 59 for us,  
4 please?

5           A.     Again, this is [REDACTED]

■ [REDACTED]  
■ [REDACTED]  
■ [REDACTED]  
■ [REDACTED]  
■ [REDACTED]  
■ [REDACTED]  
■ [REDACTED]  
■ [REDACTED]  
■ [REDACTED]

14                               (Exhibit Number 217  
15                               marked for identification.)

16           MR. MILLER: Why don't we mark as  
17 the next exhibit in order the document  
18 bearing the Bates number BRGEDEL 445191  
19 through BRGEDEL 445203.

20           DOCUMENT TECHNICIAN: That has been  
21 marked as Exhibit 217.

22           MR. MILLER: Thank you.

[illegible]

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1 Q. If you go to the lower portion --  
2 let me back up.

3 Let's go to page with the Bates  
4 number BRGEDEL 445194.

5 A. Okay.

6 Q. There is a functional specification  
7 table. It starts about halfway down the page.  
8 Do you see that?

9 A. Yes.

10 Q. And then under the general  
11 requirements for the enclosure for the design,  
12 the specification states, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

16 Do you see that?

17 A. I do see that.

18 Q. Does the NGC system that Bio-Rad  
19 sells meet this specification?

20 MR. CORREDOR: Object to the form.

21 THE WITNESS: [REDACTED]

[REDACTED]



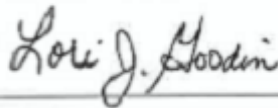
7/24/2020

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Page 657

CERTIFICATE OF COURT REPORTER

I, LORI J. GOODIN, RPR, CLR, CRR,  
CA CSR # 13959 the reporter before whom the  
foregoing deposition was taken, do hereby certify  
that the witness whose testimony appears in the  
foregoing deposition was sworn by me; that the  
testimony of said witness was taken by me in  
machine shorthand and thereafter transcribed by  
computer-aided transcription; that said  
deposition is a true record of the testimony  
given by said witness; that I am neither counsel  
for, related to, nor employed by any of the  
parties to the action in which this deposition was  
taken; and, further, that I am not a relative or  
employee of any attorney or counsel employed by  
the parties hereto, or financially or otherwise  
interested in the outcome of this action.



LORI J. GOODIN, RPR, CLR, CRR  
Notary Public in and for:

My Commission expires: May 12, 2024

STATE OF CALIFORNIA, CA CSR# 13959

My Commission expires: February 22, 2021

# **EXHIBIT 4**

**FILED UNDER SEAL**









# EXHIBIT 5



# NGC Chromatography Systems and ChromLab Software

## Instrument Guide Version 6.0



Chapman Exhibit  
7/24/2020

**211**



# **NGC Chromatography Systems and ChromLab Software**

## **Instrument Guide**

**Version 6.0**





## 1 Introduction

The NGC chromatography systems are preparative systems designed to rapidly automate the purification of biomolecules. The flexible, modular, and economical design makes NGC the instrument of choice for method development and scale-up. It is available in six preplumbed, factory-tested configurations at two different flow ranges. Each preconfigured system can be further customized and upgraded by adding valves, detectors, or pumps in order to meet specific application needs. Any system can be configured for either low flow rate or high flow rate operation by simply changing the system pump modules. As a result, a single hardware platform can be modified as the application need and scale change.

## The NGC Chromatography Systems

The NGC chromatography systems are available in a series of combinations. Each system is available with either two 10 ml system pumps (the 10 series) or two 100 ml system pumps (the 100 series).

Each system includes ChromLab software and the NGC touch screen.

- NGC Quest chromatography system includes
  - Two system pumps
  - Mixer
  - Sample injection valve
  - Conductivity monitor with a single-wavelength UV detector (on the NGC Quest system) or a multi-wavelength UV/Vis detector (on the NGC Quest Plus system)
- NGC Scout chromatography system includes
  - All modules on the NGC Quest system

**Note:** The NGC Scout system includes the single-wavelength UV detector, the NGC Scout Plus system includes the multi-wavelength UV/Vis detector.
  - pH detector
  - Buffer blending valve
- NGC Discover chromatography system includes
  - All modules on the NGC Scout system

**Note:** Only the multi-wavelength UV/Vis detector is available on the NGC Discover systems.
  - Column switching valve
  - Two buffer inlet valves
  - Sample pump

## Main Features

- NGC Discover Pro chromatography system includes
  - All modules on the NGC Discover system
  - Note:** Only the multi-wavelength UV/Vis detector is available on the NGC Discover systems.
  - Fourth expansion tier
  - Sample inlet valve
  - Outlet valve

## Main Features

NGC chromatography systems enable you to do the following:

- Easily create purification and maintenance protocols from predefined method templates and protocol phases
- Automate multicolumn purification processes using preprogrammed templates and multiple column switching valves
- Automate multiple sample injections using either the sample inlet valve and the sample pump or the C-96 autosampler
- Expand sample monitoring using the signal import module (SIM) to export digital signals to, and import digital signals from, external detectors
- Collect large-volume fractions using multiple outlet valves while also collecting small-volume fractions using the BioFrac fraction collector or NGC Fraction Collector
- Automatically prepare buffers using preprogrammed buffer blending protocols
- Analyze purification results through 1-click peak integration, determine protein concentration, and calculate column performance
- Automate purification protocol optimization using the scouting wizard
- Easily locate fractions containing peaks of interest and view the protein concentration within each fraction

## 1 | Introduction

- Extend the preconfigured systems with additional valves for buffers, samples, and columns
- Organize the location of the modules to optimize separation performance based on method scale and complexity, and to minimize the system swept volume
- Minimize errors when connecting tubing using the Point-to-Plumb feature in ChromLab software

## Site Requirements

### Power Considerations

**Note:** The power supply to the NGC system must be stable and within specifications at all times to ensure optimal operation. The power cable connected to the power inlet port must be rated for 7 amps or more.

**Table 1. Power requirements for the NGC system and ChromLab**

Parameter	Requirement
Mains input voltage	AC 100—240 V; 50—60 Hz
NGC maximum power usage	200—400 watts, dependent on system configuration
Number of power sockets	Minimum of three power sockets: <ul style="list-style-type: none"> <li>■ One socket for the NGC instrument</li> <li>■ One socket for the computer running ChromLab</li> <li>■ One socket for each fraction collector in use</li> <li>■ A socket for any supported peripheral instrument that you attach (for example, the C-96 autosampler or a second Bio-Rad fraction collector)</li> </ul> <b>Tip:</b> The touch screen does not require a separate power supply.
Type of power sockets	IEC type connections, grounded sockets



## 2 The NGC Instrument

The NGC instrument ships preassembled with the components necessary to perform gradient separations. The modular components slide into slots in the system known as *bays*. Some modules fit into single-wide bays while others require double-wide bays. Bays can be converted from one size to the other by adding or removing a center divider.

Each module has a unique electronic ID that enables the system to recognize its function when the module is placed into a bay. For example, the system can distinguish between a sample inject valve module and a sample inlet valve module even though they each occupy a single-wide slot.

The position of the module on the system can be changed to optimize the placement and minimize the length of tubing, reducing the system swept volume. The physical location of a module can be easily identified in the overall flow scheme required to run the application through the ChromLab software. Prior to starting a run, ChromLab performs a system check to ensure that all the required modules are physically present on the instrument.

This chapter explains in detail the modules that make up the NGC instrument.

## The NGC Instrument Illustrated

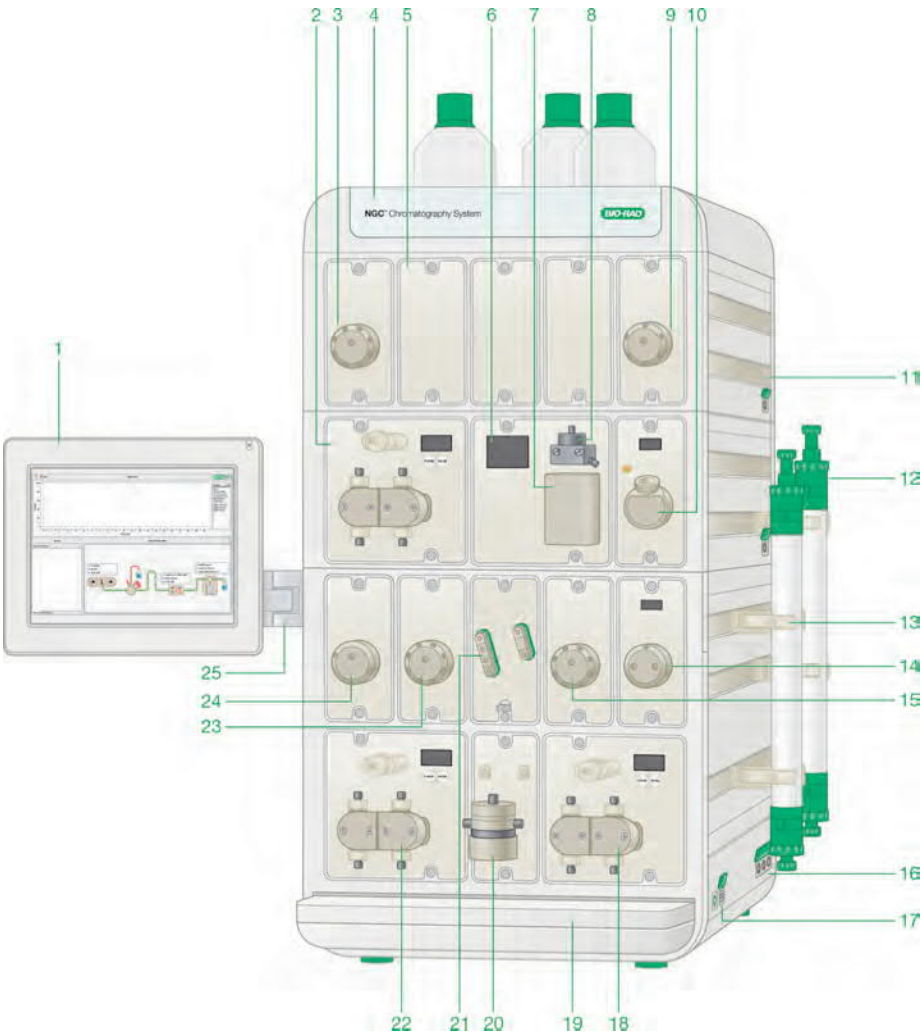
The illustrations in this section display the main components of the NGC Discover Pro chromatography system:

- Front View
- Back View
- Right Side View
- Left Side View

**Note:** Your system might not include all the modules shown in these illustrations. For a list of modules on the NGC Quest, NGC Scout, and NGC Discover chromatography systems, see Table 9 on page 87.

2 | The NGC Instrument

Front View



22 | NGC Chromatography Systems and ChromLab Software



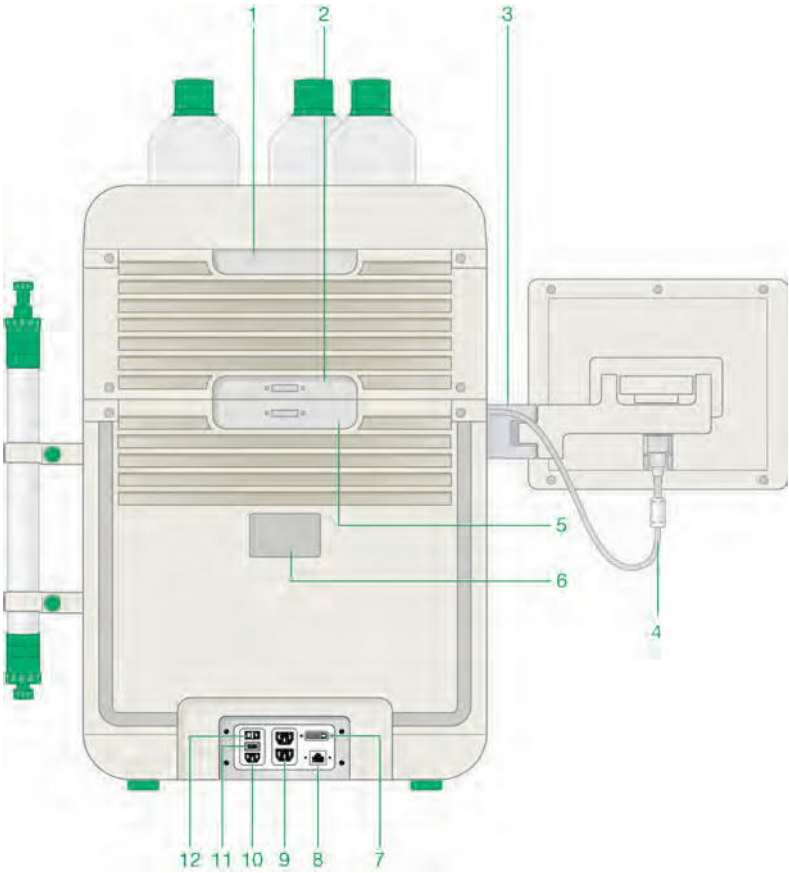
The NGC Instrument Illustrated

LEGEND

1	Touch screen monitor	2	Sample pump
3	Sample inlet valve	4	Buffer tray
5	Empty bay, covered	6	LED display
7	Multi-wavelength UV/Vis detector	8	Conductivity monitor
9	Outlet valve	10	pH detector
11	Column and peripheral mount	12	Columns
13	Column grip	14	Column-switching valve
15	Buffer inlet B	16	Peripheral ports
17	USB ports and soft power switch	18	System pump B
19	Drip tray	20	Mixer
21	Buffer blending valve	22	System pump A
23	Buffer inlet A	24	Inject valve
25	Touch screen mounting arm		

2 | The NGC Instrument

Back View

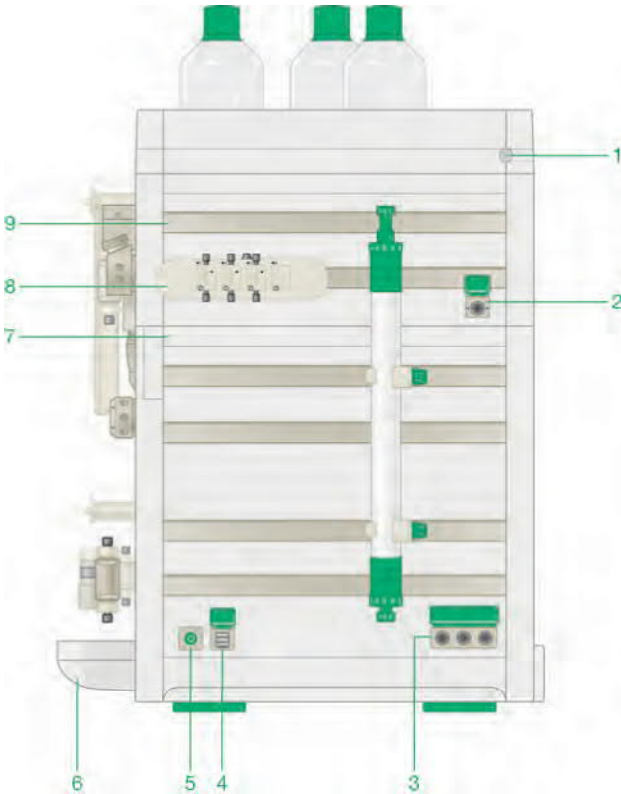


LEGEND

1	Cable connector port/hand grip	2	Cable connector port
3	Touch screen arm	4	Touch screen connector cable
5	Cable connector port/hand grip	6	Instrument's serial number label
7	Touch screen connector port	8	Ethernet connector port
9	Power outlet ports	10	Power inlet port
11	Fuse cover	12	Power on/off switch

The NGC Instrument Illustrated

Right Side View

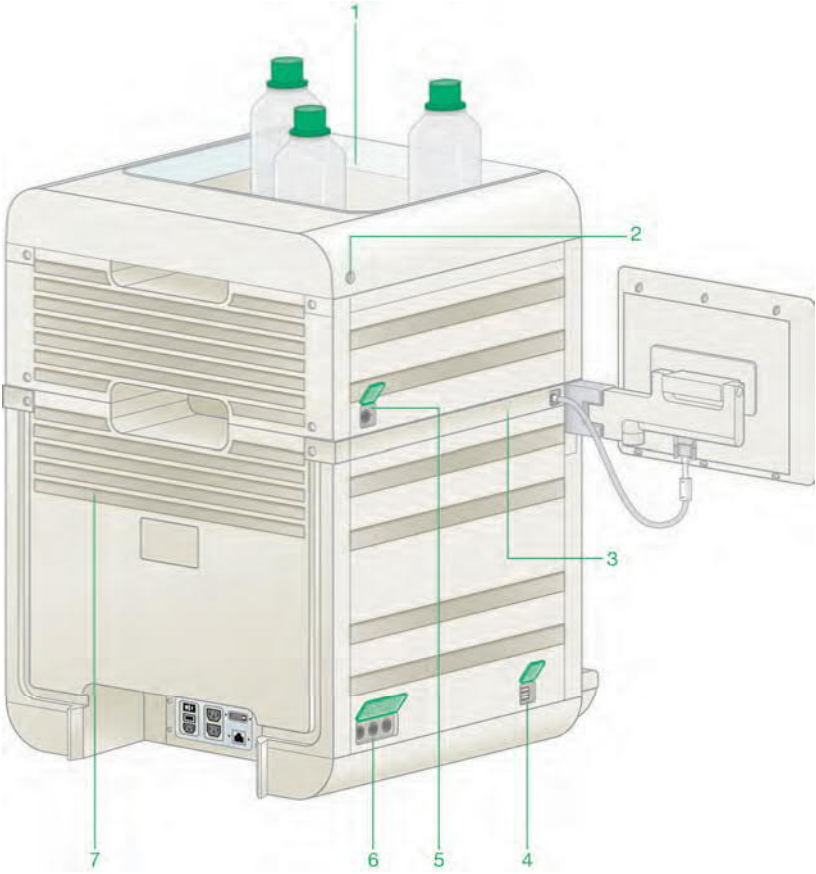


LEGEND

1	Drain hole	2	Peripheral port
3	Peripheral ports	4	USB ports
5	Soft power switch	6	Drip tray
7	Touch screen cable cover	8	Air sensor module
9	Column and peripheral mount		

2 | The NGC Instrument

Left Side View



LEGEND			
1	Buffer tray	2	Drain hole
3	Touch screen cable cover	4	USB ports
5	Peripheral port	6	Peripheral ports
7	Vents		

The NGC Instrument Illustrated

Liquid Flow Path of the NGC Discover Pro System

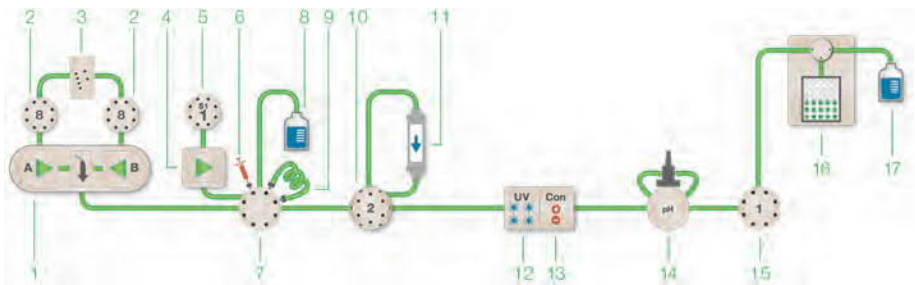
At startup, ChromLab displays a default fluidic scheme in the System Control tab (as well as in the Method Editor tab and on the touch screen). The fluidic scheme depicts the plumbing flow for the modules. The image that follows displays the plumbing flow of the modules in the NGC Discover Pro system during a sample run. The modules in the fluidic scheme are described in detail in the sections that follow.

To view or modify module parameters during a manual run

► Click the module to access its dialog box.

Alternatively, select the module on the touch screen to access its dialog box.

**Tip:** For more information about using ChromLab, see the NGC Chromatography Systems and ChromLab Software User Guide.

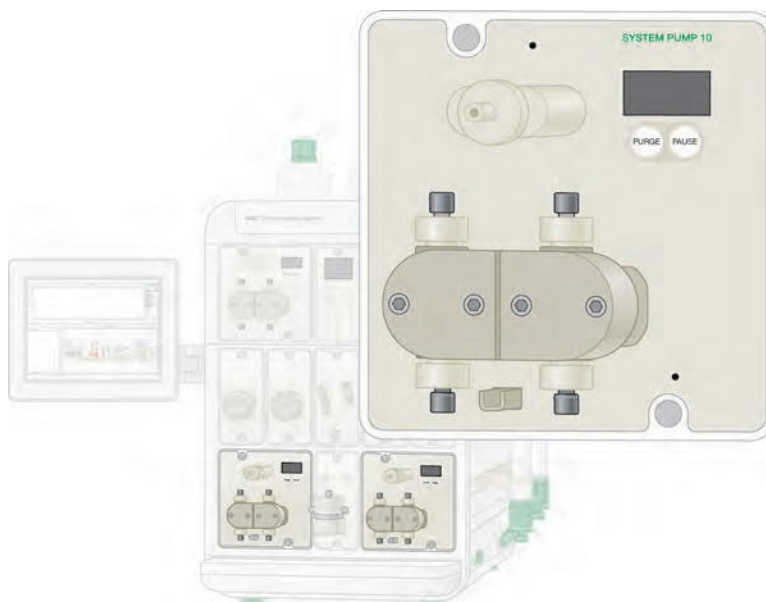


LEGEND

1	System pumps A and B	2	Buffer inlet valves A and B
3	Buffer blending valve	4	Sample pump with pressure sensor
5	Sample inlet valve	6	Manual inject syringe
7	Sample inject valve	8	Waste (not provided)
9	Sample loop	10	Column switching valve
11	Column (not provided)	12	Multi-wavelength UV/Vis detector
13	Conductivity monitor	14	pH valve
15	Outlet valve	16	Fraction collector (separate instrument)
17	Waste (not provided)		

## Pumps

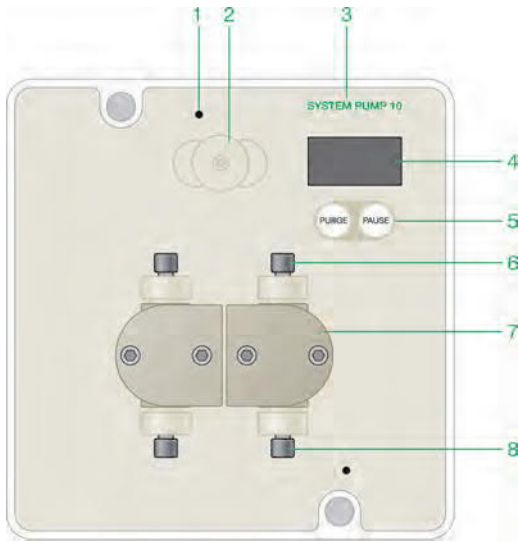
The NGC systems can have up to three high-precision pumps: two system (or gradient) pumps (pump A and pump B) and one sample pump. The system pumps can create isocratic or linear gradients at a range of precisely controlled flow rates and pressures. The sample pump can load large sample volumes onto a column or fill large sample loops. Flow rates on all pumps can be controlled to avoid overpressure.



Pumps

System Pumps

The system pumps perform isocratic or gradient elution at the specified flow rates.



LEGEND			
1	Pump flow status LED	2	Priming port
3	Module name	4	LED screen
5	Purge/pause buttons	6	Pump outlet port
7	Pump head	8	Pump inlet port

### Detailed Attributes

The NGC systems include two system pumps: pump A (the left pump) and pump B (the right pump). The system pumps are available in two flow rates: 10 ml/min (the F10 pumps) and 100 ml/min (the F100 pumps).

#### F10 Pump

- Flow rate delivery: 0.001–10 ml/min specified
- Operating pressure range: 0–3,650 psi (0–25.2 MPa)
- Operating viscosity range: 0.35–10 cP

#### F100 Pump

- Flow rate delivery: 0.01–100 ml/min specified
- Operating pressure range: 0–1,450 psi (0–10 MPa)
- Operating viscosity range: 0.35–10 cP

### System Pump LEDs

Each system pump module is fitted with LEDs.

- Green LEDs indicate the pump is in use.

### How the System Pumps Function

Each NGC system ships with either two F10 pumps or two F100 pumps. The reciprocating pistons in each pump synchronize to deliver continuous flow with low pulsation. On the NGC Quest system (without a buffer blending valve), the system pumps operate such that the sum of the flow rates of pump A and pump B is equal to the maximum delivery rate. For example, if the flow of an F10 pump A equals 10 ml/min, then the rate for the F10 pump B must equal 0 ml/min. If the system is set to deliver 5 ml/min with a gradient mixture of 50% B, pump A and pump B each run at 2.5 ml/min.



## Pumps

Each system pump module has an emergency Pause button and a Purge button.

- Pressing the emergency Pause button on either system pump stops *both* pumps. If a run is in progress when you press Pause on either system pump, both system pumps stop and the run pauses.

You can resume or cancel the run through ChromLab. If you choose to cancel the run, you can save the run data up to that point.

- Pressing Purge on a system pump runs that pump at full speed, replacing any air in the lines with buffer. Purge activates purging for the tubing lines that belong to that specific pump. For instance, when you press Purge on system pump A, pump A runs at maximum flow rate while pump B becomes idle. If you press Purge on pump B while pump A is purging, the purge on pump A stops and the purge on pump B starts. The Purge button is a toggle. To stop the purge, press Purge on that system pump again.

**Note:** The Purge button is deactivated when:

- A run is in progress
- Any of the modules are in calibration mode
- The buffer blending valve is included in the fluidic scheme



**Caution:** To avoid damaging the column, always ensure that it is offline when purging the system. Set the inject valve to waste, or remove the column from the system and replace with a union fitting.

**Tip:** You can pause the system through ChromLab using either the touch screen or the computer running ChromLab (known in this document as the ChromLab computer). You can also set timed purging of both pumps through ChromLab, which will set the inject valve to Waste for a set amount of time. For more information, see the NGC Chromatography Systems and ChromLab Software User Guide.

### Pump Priming Port

The pump priming port introduces fluid into, and removes air from, the inlet tubing line and the pump head.

### **Piston Wash System**

The pumps on the NGC system automatically rinse behind the piston with a constant low flow of 20% ethanol. This prolongs the working lifetime of the seal by keeping the seal wetted and preventing salt crystals from depositing onto the pistons.

When the pumps are running, the pistons and the check valve located in each chamber automatically pump the rinse fluid, which circulates through the system. The tube holders on the side of the instrument hold two conical rinsing solution reservoirs, one for the system pumps and one for the sample pump (if present). The inlet and outlet tubing for the system pumps piston wash housing is immersed in one of the rinsing solution reservoirs. The inlet and outlet tubing for the sample pump is immersed in the second rinsing solution reservoir. The tubing connects to the wash housing ports at the back of the pump heads.

**Important:** Change the rinse fluid weekly. Place the washing system reservoir at the same height or above the level of the pump heads to avoid siphoning of the solution back to the reservoir. Ensure that the inlet tubing reaches the very bottom of the rinsing solution reservoir.

## Valves

All NGC systems include a sample inject valve. Your system might also include one or more of the following valves:

- Buffer blending valve
- Buffer inlet valve
- Sample inlet valve
- Outlet valve
- Column switching valve

All valves (except the buffer blending valve) are motorized rotary valves with a number of defined inlet and outlet ports. As the rotary valve turns, the flow path for the valve changes. The active ports are identified by LEDs. Green LEDs indicate that the flow through the port is from the system pumps. Blue LEDs indicate that the flow is from the sample pump. The pattern and location of the ports determine the flow path and function of each type of valve.

**Tip:** Bio-Rad recommends inserting a Delrin or Tefzel 1/4–28 flat-bottom plug, included in the fittings kit, into unused valve ports to prevent particles from entering the valve.

Valves

### Sample Inject Valve

The sample inject valve enables the system to load a specific, predetermined volume of sample onto a column.

When the sample pump is installed, the sample inject valve enables the system to easily switch between manual loop filling, automated loop filling, and direct sample injection onto a column without replumbing the fluidic connections.

You can use the sample pump to load sample either directly onto a column or into a sample loop.



### Detailed Attributes

- Maximum operating pressure is 3,650 psi

Ports on the Sample Inject Valve



Port	Function
Inject	Manually load sample using a syringe
Column	Outlet to top of column
Pump	Inlet from the system pump
Loop E	<div>■ Inject: Inlet for buffer</div> <div>■ Load: Outlet to waste</div>
Waste 1	Outlet to waste (from the sample pump and sample loop)
Sample pump	Inlet from the sample pump
Loop F	<div>■ Inject: Outlet to column</div> <div>■ Load: Inlet for the sample</div>
Waste 2	Outlet to waste (from the system pump)

## Valves

### Sample Inject Valve LEDs

The sample inject valve module is fitted with LEDs.

- Solid green LEDs indicate the flow is from the system pump.
- Solid blue LEDs indicate the flow is from the sample pump.
- Blinking green LEDs indicate the line to plumb using the Point-to-Plumb feature.

### How the Sample Inject Valve Works

The sample inject valve enables sample to be loaded onto the column. Several sample application techniques are available:





- The sample loop can be manually filled with sample using a syringe followed by injection onto a column by the system pumps
- The sample loop can be filled with sample using the sample pump (if installed) followed by injection onto a column by the system pumps
- Sample can be injected directly onto the column using the sample pump (if installed)

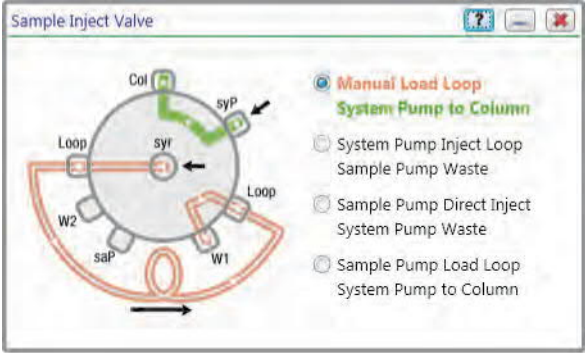
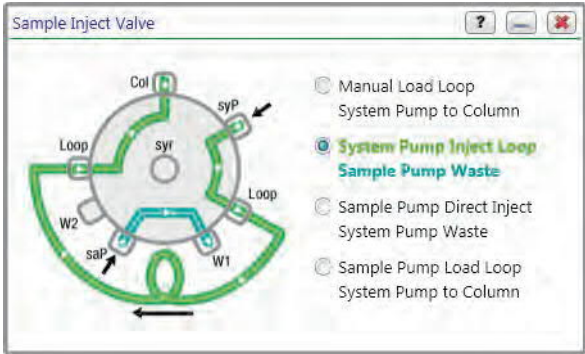
### Flow Paths of the Sample Inject Valve

In Manual mode (from the System Control tab in ChromLab), you can manually change the flow path of the sample inject valve from its dialog box.

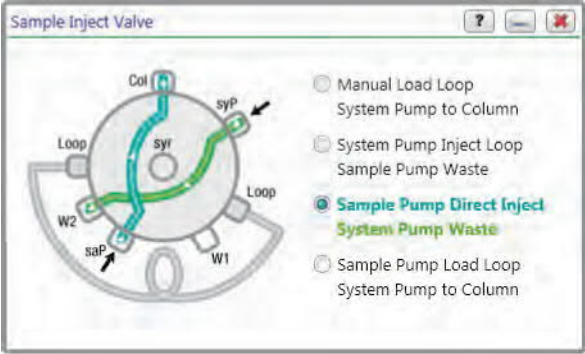
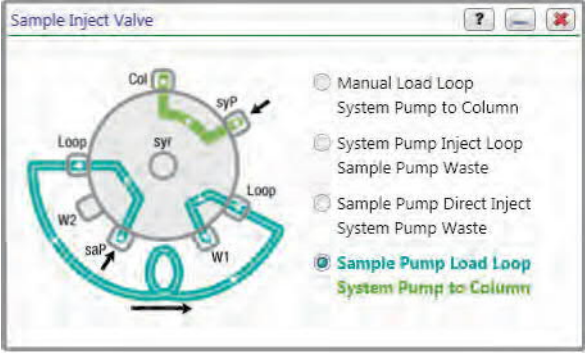
The following images show the different flow paths of the sample inject valve.

#### LEGEND

	Manual injection flow
	System pump flow
	Sample pump flow
	No flow

Valve Position	Explanation
<b>Manual Load Loop/System Pump to Column</b>	
	<ul style="list-style-type: none"><li>■ Directs system pump flow directly toward the column</li><li>■ Aligns the sample loop with manual injection port so that sample can be manually filled into the loop using a syringe. Excess sample goes out waste port (W1)</li><li>■ Chromatogram x-axis based on system pump flow rate</li></ul>
<b>System Pump Inject Loop/Sample Pump Waste</b>	
	<ul style="list-style-type: none"><li>■ Directs system pump flow through the sample loop to load the sample from the loop onto the column</li><li>■ Directs sample pump flow to waste (W2)</li><li>■ Chromatogram x-axis based on system pump flow rate</li></ul>

Valves

Valve Position	Explanation
<b>Sample Pump Direct Inject/System Pump Waste</b>	
	<ul style="list-style-type: none"><li>■ Directs system pump flow to waste (W2)</li><li>■ Directs sample pump flow directly onto the column to load large volumes of sample</li><li>■ Chromatogram x-axis based on sample pump flow rate</li></ul>
<b>Sample Pump Load Loop/System Pump to Column</b>	
	<ul style="list-style-type: none"><li>■ Directs system pump flow directly onto the column</li><li>■ Directs sample pump flow into the loop to load the loop with sample. Excess sample flows out through waste port (W1)</li><li>■ Chromatogram x-axis based on system pump flow rate</li></ul>



## Detectors

### Mixer LEDs

The mixer module is fitted with LEDs.

- A left green LED indicates the flow is from system pump A.
- A right green LED indicates the flow is from system pump B.
- Both LEDs light when both pumps are running.
- Blinking green LEDs indicate the line to plumb using the Point-to-Plumb feature.

## Detectors

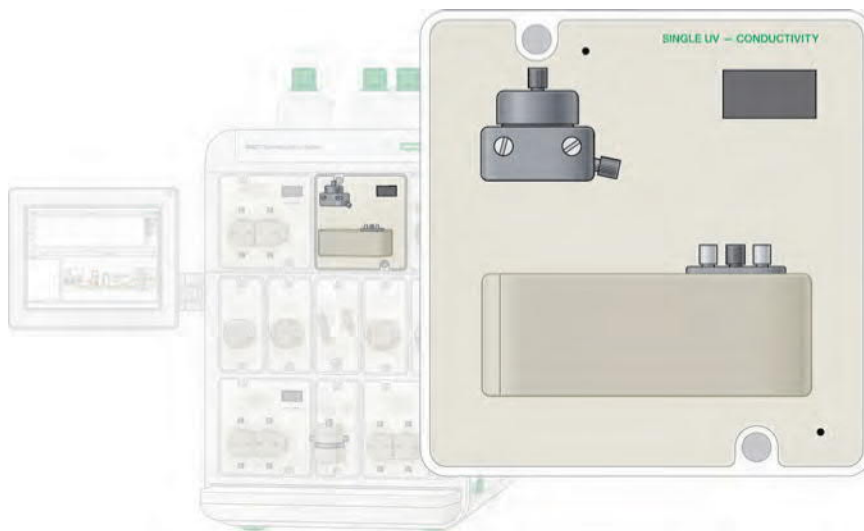
All NGC systems include a detector module that contains a conductivity monitor and either a single-wavelength UV detector or a multi-wavelength UV/Vis detector. The single-wavelength UV detector and conductivity module can be replaced with a multi-wavelength UV/Vis detector and conductivity module and vice versa. Some configurations include a pH detector module. The pH detector module can be added as an upgrade to systems that do not offer it as a standard module.

### UV Detectors and Conductivity Monitor

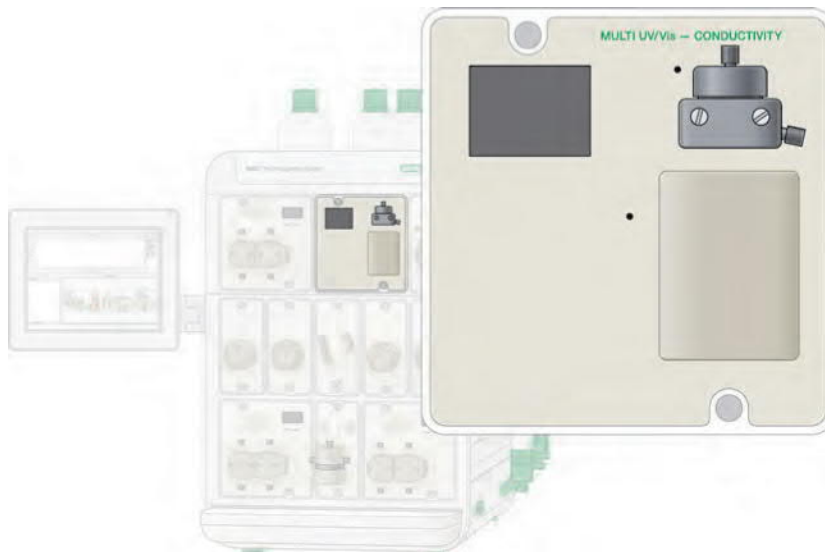
The UV detectors measure the UV absorbance of biomolecules as they elute through the column. The conductivity monitor measures the ionic strength (salt concentration) of buffers.

2 | The NGC Instrument

**Single-Wavelength UV Detector and Conductivity Monitor**

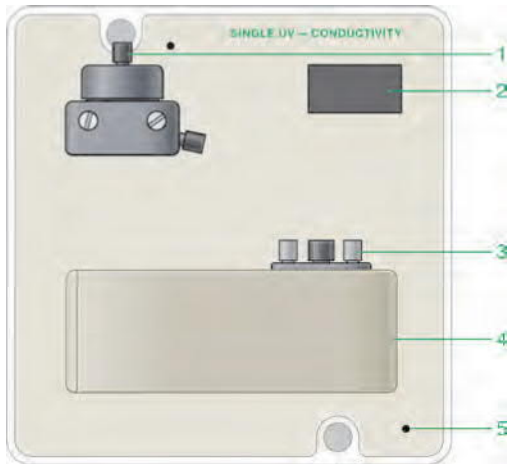


**Multi-Wavelength UV Detector and Conductivity Monitor**



Detectors

Single-Wavelength UV Detector



LEGEND

1	Conductivity monitor	2	LED display
3	UV flow cell	4	UV detector housing
5	Point-to-Plumb indicator		

Detailed Attributes

- Two integrated LED UV bulbs
- LED operating usage: approximately 5,000 hours

**Note:** If the reference output is below 0.9 volts you might need to replace the LED bulbs depending on the requirements of the experiment.

For information about changing the LED bulbs, see [Replacing the Single-Wavelength UV Detector LED on page 207](#).

2 | The NGC Instrument

- Monitors UV absorbance one wavelength at a time

- 255 nm
- 280 nm (default)

**Tip:** Use ChromLab to change the absorbance wavelength values. For more information, see the NGC Chromatography Systems and ChromLab Software User Guide.

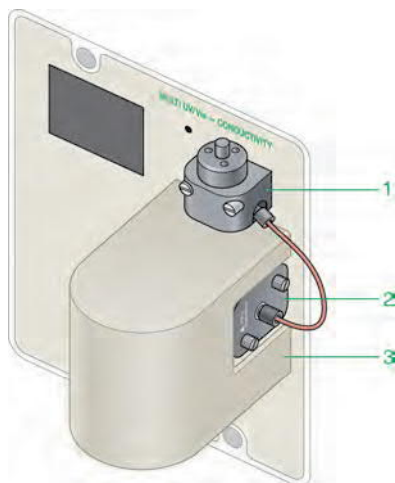
- UV absorbance range: 0–3,000 mAU
- UV linearity:  $\pm 5\%$
- Three interchangeable flow cells with path lengths of 2 mm, 5 mm (default), and 10 mm; see Table 4 on page 70 for specific information

**Note:** Use the preparative 2 mm flow cell to measure high concentrations of protein. The path lengths of the analytical 5 mm and 10 mm flow cells are longer and are appropriate for measuring lower concentrations of protein.

For information about changing the flow cells, see [Replacing the UV Flow Cell on page 202](#).

Detectors

### Multi-Wavelength UV/Vis Detector



#### LEGEND

- |   |                         |   |                           |
|---|-------------------------|---|---------------------------|
| 1 | Conductivity monitor    | 2 | UV/Vis detector flow cell |
| 3 | UV/Vis detector housing |   |                           |

#### Detailed Attributes

- Contains one tungsten and one deuterium lamp
- Lamp operating usage: approximately 2,000 hours for the tungsten bulb as well as the deuterium bulb

For information about changing the UV lamps, see [Replacing the Multi-Wavelength UV/Vis Detector Lamps on page 215](#).

**Tip:** To conserve lamp life, in Manual mode open the Multi Wave Detector dialog box and turn off the UV/Vis lamps when the instrument is not in use.

## 2 | The NGC Instrument

- Monitors up to four wavelengths in the UV/Vis range of 190–800 nm

**Tip:** Use ChromLab to change the absorbance wavelength values. For more information, see the NGC Chromatography Systems and ChromLab Software User Guide.

- UV absorbance range: 0–3,000 mAU
- UV linearity:  $\pm 5\%$
- Three interchangeable flow cells with path lengths of 2 mm, 5 mm (default), and 10 mm; see Table 4 for specific information

For information about changing the flow cells, see [Replacing the UV Flow Cell on page 202](#).

**Note:** Use the preparative 2 mm flow cell to measure high concentrations of protein. The path lengths of the analytical 5 mm and 10 mm flow cells are longer and are appropriate for measuring lower concentrations of protein.

Table 4. Pressure limits of UV detector flow cells

Pump Size	Pressure	2 mm	5 mm	10 mm
F10	500 psi	✓	✓	✓
F100	500 psi	✓	✓	✓

## Conductivity Detector

### Detailed Attributes

- Factory specified range: 0.01–999.9 mS/cm
- Validated working range: 0.01–300 mS/cm
- Accuracy:  $\pm 2\%$
- Flow cell volume: 6  $\mu$ l
- Integrated temperature sensor range: 4–100°C

## Detectors

### How They Work

#### UV Detectors

ChromLab recognizes the connected optic module (that is, either the single-wavelength UV or multi-wavelength UV/Vis module). The lamps turn on when the NGC instrument powers up. At the start of the method run, the system determines if the monitor is ready.

The warmup time for the LED lamp in the single-wavelength detector is negligible. The tungsten and deuterium lamps in the multi-wavelength detector require 60–90 min to warm up.

**Note:** For most accurate data with the tungsten and deuterium lamps, allow a minimum of 60 min warmup time.

#### Conductivity Monitor

The temperature-compensated conductivity monitor calculates the conductivity of the sample and buffer mixture flowing through its flow cell. The stronger the salt concentration, the higher the conductivity signal.

Since conductivity of a solution can vary with changes in temperature, temperature variations of the sample are measured by the temperature sensor located in the conductivity flow cell. A temperature compensation factor (set in ChromLab) can be used to compare the conductivity of the sample in relation to the corresponding conductance at room temperature or a user-defined reference temperature.

## Detectors

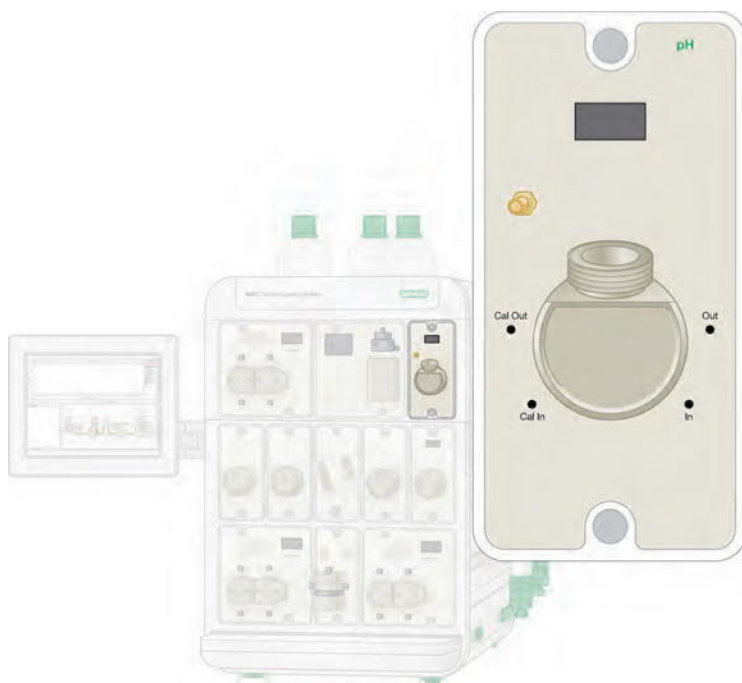
### pH Detector

The pH detector includes an integrated flow cell in which to insert a pH electrode. The pH of the solution flowing across the pH electrode is measured in real time. This is very useful for applications in which knowledge of the buffer pH is critical for a successful separation and/or the stability of the sample (for example, in antibody purifications). The pH can be temperature compensated.

The pH valve directs the flow to either

- pH — flow path is inline with the pH probe, or
- Bypass — flow path bypasses the electrode

**Note:** In Calibrate mode, the pH electrode is offline for calibration.





2 | The NGC Instrument

### Detailed Attributes

- Flow cell volume: 90  $\mu$ l (200  $\mu$ l including internal valve passageways)
- Electrode maximum operating pressure: 70 psi
- pH reading range: 0–14
- Accuracy: 0.1 pH units from 2–12
- Slope: 80–120%
- Offset:  $\pm$ 60 mV

**Note:** Store the electrode in a pH electrode storage buffer or pH 7 standard buffer. For information about changing the pH probe, see [Replacing the pH Probe on page 224](#).

### Ports on the pH Detector



## Detectors

Port	Description
In	Inlet from the conductivity monitor
Out	Outlet to the fraction collector
Cal In	Calibration inlet reserved for calibrating the pH valve
Cal Out	Outlet to calibration waste

### How the pH Detector Works

The integrated pH electrode enables inline pH monitoring during a run. ChromLab calculates and displays temperature-compensated pH values.

You can program the position of the pH valve in ChromLab to direct the flow to the pH electrode, or to bypass the electrode. The section [Changing the Flow Paths of the pH Valve on page 76](#) explains how to change the flow path.

The pH valve has an integrated calibration port to calibrate the probe offline without disconnecting the module from the system. Calibration is performed using calibration standards in ChromLab. For more information, see [Calibrating pH on page 150](#).

### Changing the Flow Paths of the pH Valve

During a manual run, you can change the flow path of the pH valve by accessing its dialog box in ChromLab.

#### To change the flow path of the pH valve

1. Touch or click the pH Valve module in the fluidic scheme to access its dialog box.



2. In the pH Valve dialog box, select the appropriate choice:
  - pH — the flow path is inline with the pH probe
  - Bypass — the flow path bypasses the pH probe

## Tubing, Loops, Columns, and Fittings

This section lists the accessories supported for use with the NGC systems.

### Tubing

Table 5. NGC system tubing details

Description	Diameter	Scope of Use	Maximum Pressure Rating	Mounted at Delivery
PEEK tubing, orange	OD: 1/16" ID: 0.020"	High pressure tubing, recommended for flow rates less than 40 ml/min	6,000 psi	Yes
PEEK tubing, green	OD: 1/16" ID: 0.030"	High pressure tubing	4,000 psi	Yes
Polytetrafluoroethylene (PTFE) tubing, transparent	OD: 1/8" ID: 0.062"	Inlet tubing	500 psi	No
Tefzel tubing, transparent	OD: 1/16" ID: 0.020"	Waste	4,000 psi	No

## Sensors

### Air Sensors

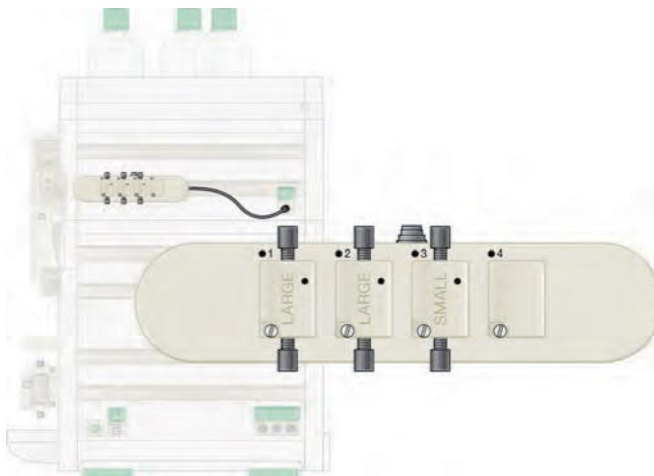
The NGC chromatography systems can be fitted with an external air sensor module that can hold up to four air sensors. This module can be daisy chained to an extension module that can hold an additional four air sensors, providing a total of eight air sensors. The air sensors detect air, indicating the end of sample or buffer, and trigger appropriate events through ChromLab software. The air sensors are available in two sizes that differ in internal diameter to accommodate the two different tubing sizes:

- The large air sensors are used with the larger diameter 1/8" FEP tubing for the inlet ports of the pumps and inlet valves.
- The smaller air sensors are used with the smaller diameter 1/16" PEEK tubing.

The systems detect the number of air sensors that are attached to the instrument. Air sensors can be set to detect air in lines filled with buffer. If air is detected in these lines, the system pumps stop and the run pauses. You can continue the run after replenishing the buffer and purging the lines.

Air sensors can also be set to detect air in lines filled with sample. If air is detected in these lines, the sample pump stops so that it cannot pump air onto the column. If an air-bubble sensing event occurs during a method run, the run continues to the next step.

2 | The NGC Instrument



The air sensors are inserted into ports on the air sensor module. ChromLab detects the presence or absence of air sensors in the air sensor module. If you have fewer than four air sensors in the module, you must cover the unoccupied ports with a protective blank cover that Bio-Rad provides to prevent liquid from entering into the module's electronic circuitry.

The air sensors can be connected to

- The inlet port on the sample pump
- The inlet port on system pump A
- The inlet port on system pump B
- Any position along the flow path of the instrument, for example
  - Sample inject valve
  - Buffer inlet valve

## Sensors

**Air Sensor LEDs**

The air sensor module is fitted with LEDs.

- Green LEDs indicate the module is connected.
- Blue LEDs indicate air in the tubing.

Prime the lines to remove air. See [Priming and Purging the Systems on page 123](#) for more information.

**Air Sensor Tubing Length and Bubble Size**

The response of the air sensor module is highly dependent on the bubble size and flow rate, and requires a minimum tubing length between the sensor outlet and the pump inlet. Table 8 lists recommended tubing lengths for various flow rates and bubble sizes.

**Table 8. Recommended air sensor tubing lengths**

Flow Rate	Bubble Size	1/8" ID FEP Tubing Length (air sensor to pump inlet)
1 ml/min	15–25 $\mu$ l	$\geq 6"$
5 ml/min	50–100 $\mu$ l	$\geq 6"$
10 ml/min	200 $\mu$ l	$\geq 6"$
100 ml/min	1.05–1.4 ml	$\geq 42"$

## Pressure Sensors

The NGC systems can have up to four integrated pressure sensors:

- System pressure sensor — located in the mixer module
- Precolumn and postcolumn pressure sensors — located in the column switching valve

These pressure sensors protect the column and media from overpressure. One pressure sensor measures the pressure before the column to protect the column hardware. The other sensor measures the pressure after the column and calculates the pressure difference over the media bed. If the pressure differential value (Delta P) exceeds the preset limit, either the run pauses or another action is applied.

- Sample pump pressure sensor — located in the sample pump module

Each pressure sensor has an accuracy of  $\pm 2\%$  or 2 psi, whichever is smaller.

## Temperature Sensor

The NGC systems have an integrated temperature sensor located in the conductivity flow cell that measures the run temperature. Sensor data is used for temperature compensation of conductivity and pH.



## Product Configurations

## Product Configurations




The NGC chromatography system is available in four standard configurations. This section lists the modules available for each configuration. You can add or remove modules to an existing configuration to customize the system. The configuration at your site might differ slightly from any of the standard configurations.

**Note:** All NGC systems are available with *either* the 10 ml/min or the 100 ml/min system pumps.

**Table 9. NGC chromatography system configurations**

Module	NGC Quest	NGC Scout	NGC Discover	NGC Discover Pro
Sample injection valve	✓	✓	✓	✓
Single-wavelength UV and conductivity monitor (Available on the NGC Quest and NGC Scout systems only)	✓	✓		
Multi-wavelength UV/Vis and conductivity monitor (Available on all NGC systems)	✓	✓	✓*	✓*
System pumps A and B	✓	✓	✓	✓
Mixer	✓	✓	✓	✓
pH valve		✓	✓	✓
Buffer blending valve		✓	✓	✓
Column switching valve 1			✓	✓
Sample pump			✓	✓
Buffer inlet valves A and B			✓	✓
Third expansion tier			✓	✓

Table 9. NGC chromatography system configurations, continued

Module	NGC Quest	NGC Scout	NGC Discover	NGC Discover Pro
Fourth expansion tier				
Sample inlet valve 1				
Outlet valve 1				
*Only the multi-wavelength UV/Vis detector is available in the NGC Discover series.				



## 3 Preparing the Instrument

The NGC instruments ship preassembled with the modules necessary to perform chromatographic separations. The instruments require minimal postinstallation setup to prepare them to run simple gradient separations. This chapter explains how to prepare the NGC systems for a method run.

Module Review

The NGC systems are shipped in one of three standard configurations. Preparing the NGC systems differs slightly depending on the configuration.

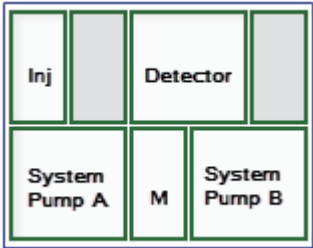
**Tip:** For information about adding, removing, or moving modules, see [Replacing or Repositioning Modules on the NGC Instruments on page 233](#).

Standard NGC System Configurations

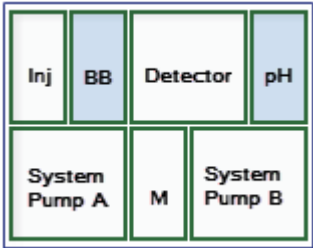
The standard NGC system configurations are depicted in the images that follow. Table 9 on page 87 lists specific information about each configuration.

**Note:** Each configuration can be converted to another by adding or removing modules. The configuration at your site might differ slightly from the configurations shown below.

NGC Quest Chromatography System

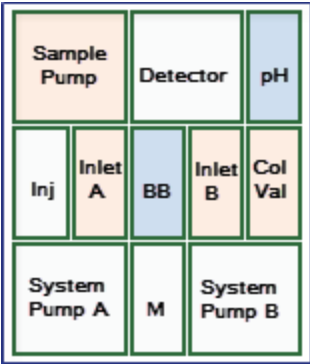


NGC Scout Chromatography System

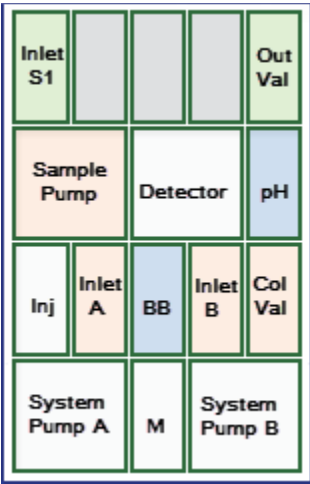


Module Review

NGC Discover Chromatography System



NGC Discover Pro Chromatography System



## NGC Systems Accessories Kit

Each NGC system ships with an accessories kit. The contents of the kit are specific to the system. Verify the contents against those listed in the sections that follow.

The accessories kits contain the tubing, loops, and fittings necessary to complete the setup of the shipped configuration. All kits include

- NGC fittings kit
- 1 ml syringe
- Luer adapter
- Fittings tightener
- Touch screen and pivot arm kit
- Tool to attach touch screen
- Pump head wash inlet tubing (2)
- Pump head wash priming line
- 1/4-28 union
- System pump inlet tubing (2)
- 1 ml sample loop
- Waste tubing (2)
- Injection port
- 20 psi backpressure regulator
- Tubing retainers, small (1, for PEEK tubing management)
- Tubing retainers, large (2, for PTFE tubing management)
- Column tubing (2) and fittings (from inject valve to column top and from column bottom to UV detector inlet)
- Tube #2 (conductivity flow cell to 20 psi backpressure regulator)
- Tube #4 (backpressure regulator to the NGC Fraction Collector (NGC FC) or BioFrac fraction collector)

## NGC Systems Accessories Kit

### NGC Scout Accessories Kit

The kit for the NGC Scout system includes all the accessories in the NGC systems kit as well as

- Tube #2 (20 psi backpressure regulator to pH valve inlet)
- pH waste tubing
- pH calibration port inlet tubing
- Colored tubing for the buffer blending valve

### NGC Discover Accessories Kit

The kit for the NGC Discover system includes all the accessories in the NGC Scout kit as well as

- Pump head wash inlet tubing (2) for the sample pump
- Pump head wash priming line for the sample pump
- 1/4-28 union
- Sample pump inlet tubing
- System pump inlet tubing (14) for inlet valves
- Column tubing (10) and fittings (from the column switching valve Top positions to column top, and from column bottom to column switching valve Bottom positions)

### NGC Discover Pro Accessories Kit

The kit for the NGC Discover Pro system includes all the accessories in the NGC Discover kit as well as

- Buffer inlet tubing (8) for inlet valve
- Tube #6 for the inlet valve
- Outlet valve tubing (12) for the outlet valve
- Tube #10 for the outlet valve

## The Detectors

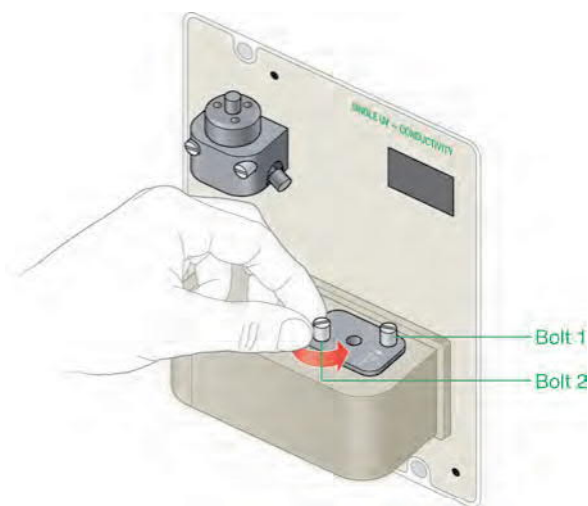
### Replacing the UV Flow Cell

The NGC systems ship with a 5 mm UV flow cell installed. Additional flow cells for analytical (10 mm) and preparative (2 mm) applications are available. This section explains how to change or replace the UV flow cell. The procedure is the same for both the single-wavelength UV and multi-wavelength UV/Vis detectors.

#### To replace the UV flow cell

1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. Disconnect the inlet and outlet tubings from the UV cell.
3. With the screwdriver supplied in the fittings kit, loosen the two bolts on the UV flow cell.

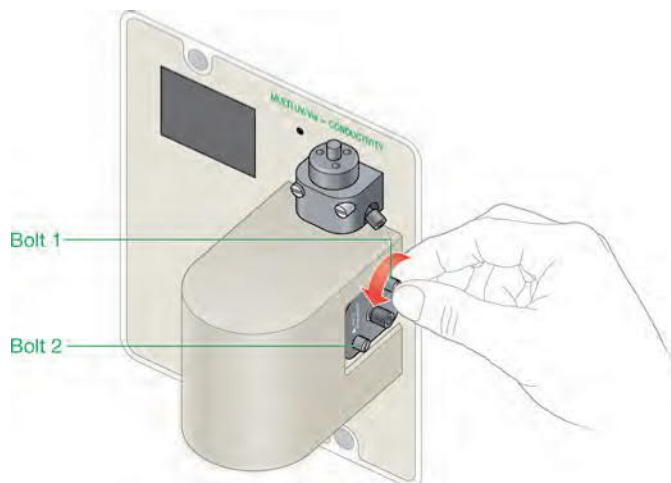
#### Single-Wavelength UV Flow Cell





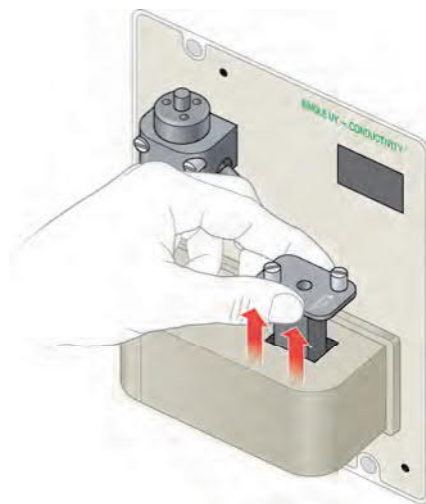
The Detectors

**Multi-Wavelength UV/Vis Flow Cell**



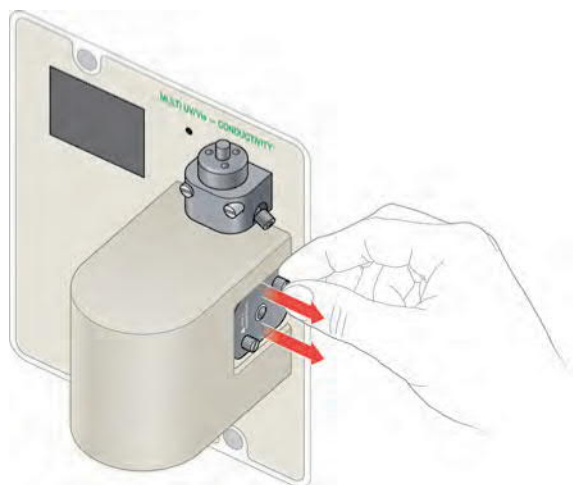
4. Firmly grasp the bolts on the flow cell and lift the flow cell from its socket.

**Single-Wavelength UV Flow Cell**



A | Maintaining the Instrument

**Multi-Wavelength UV/Vis Flow Cell**



5. Verify that the square gasket is removed with the flow cell.

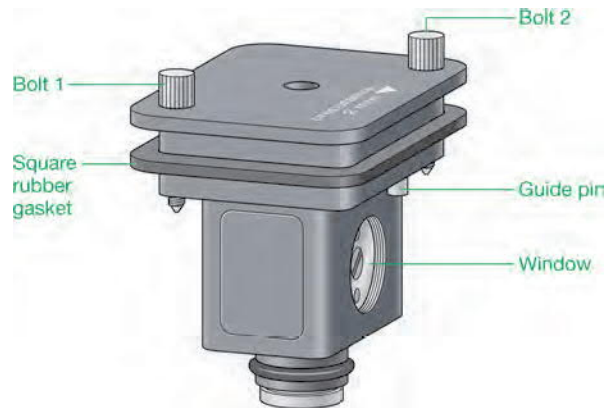
**Tip:** If the gasket is not on the flow cell, look inside the socket. The rubber gasket might have remained in the groove inside the socket. Remove the gasket and place it onto the flow cell that you removed.

6. Store the flow cell with the attached gasket and bolts in a safe, clean place for future use.

## The Detectors

7. Locate the flow cell. The flow cell should include

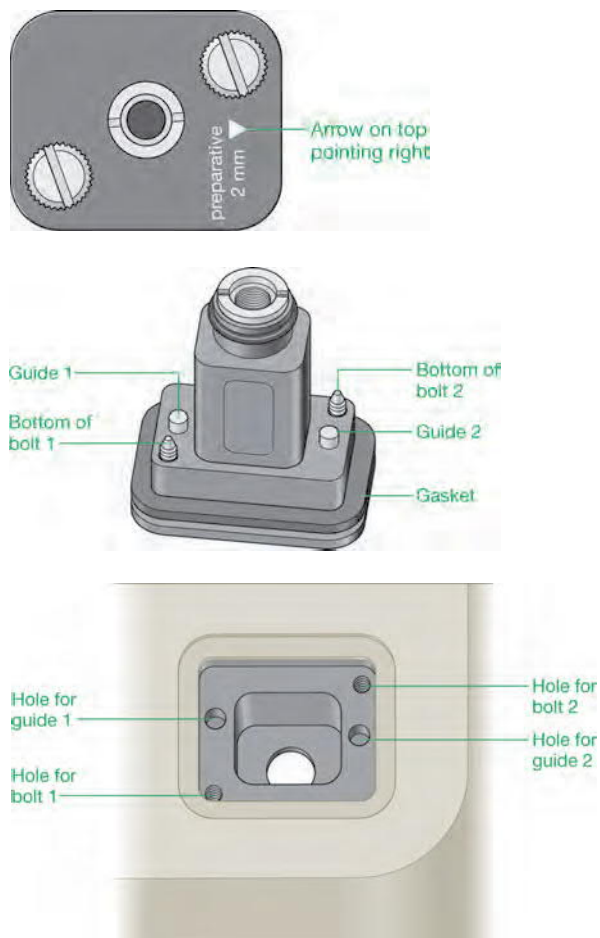
- Two bolts
- One square rubber gasket



8. Place the flow cell into the socket on the UV monitor.

**Note:** Ensure that the arrow on the top of the flow cell is pointing to the right, and that the two bolts on the flow cell align with the bolt holes in the socket. The guides on the bottom of the flow cell help to prevent inserting the flow cell incorrectly.

A | Maintaining the Instrument



9. Tighten the bolts. If necessary, use the screwdriver.
10. Reconnect the 1/4-28 fittings from the tubing to the top and bottom of the flow cell and ensure that they are secure.
11. Reconnect the tubing lines to the conductivity monitor.
12. Restart the NGC instrument.

## Replacing the Single-Wavelength UV Detector LED

This section explains how to replace the LED on the single-wavelength UV detector.



**Caution:** It is strongly suggested that you wear gloves when you replace the LED. Do not touch the LED glass with bare hands, as oils from your skin will degrade the lamp over time.

### To replace the single-wavelength UV LED

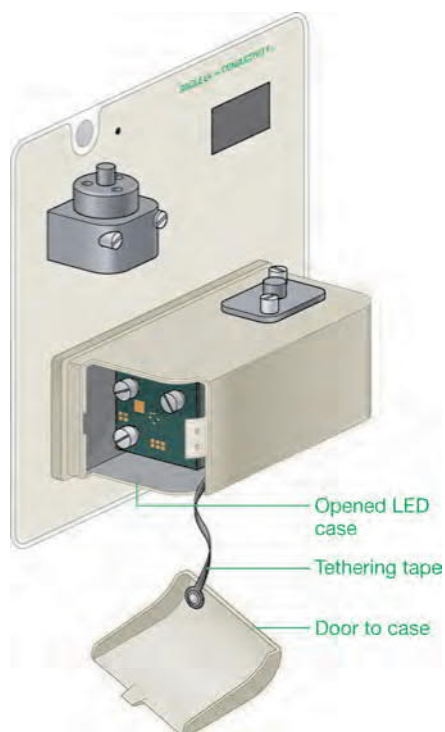
1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. Disconnect the tubing lines from the top and bottom of the UV cell.
3. Disconnect the tubing lines from the conductivity monitor.
4. The door to the LED is held in place by a pressure latch. Press down on the latch and then slide the door forward.

A | Maintaining the Instrument



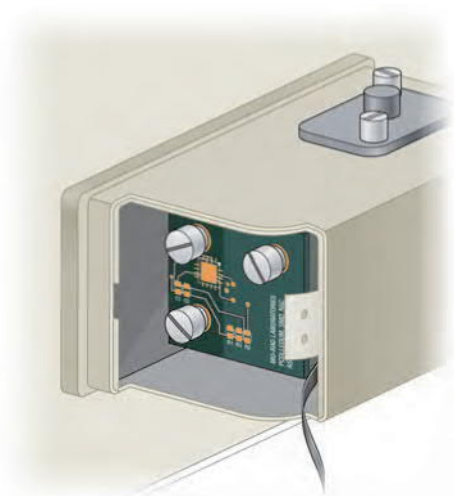
## The Detectors

**Tip:** The door is tethered to the casing. It will hang to the side while you replace the lamps.



A | Maintaining the Instrument

You see the LED module with three thumbscrews. The LED itself is on the other side of the board.



5. Completely loosen the top right thumbscrew.

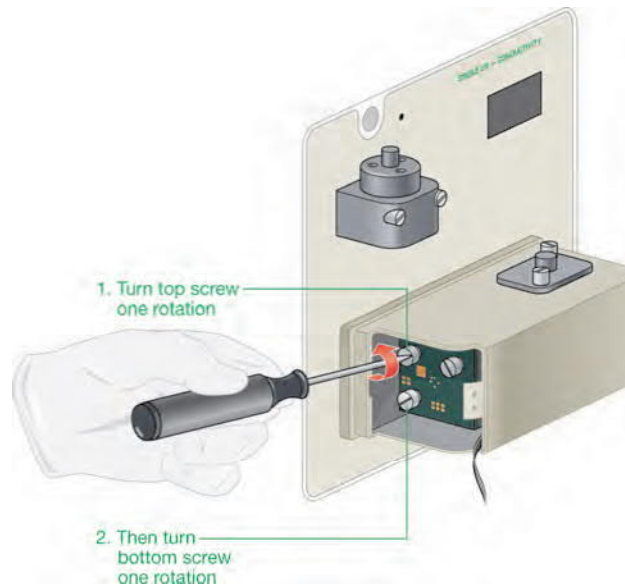




The Detectors

6. Loosen the left thumbscrews, alternating one turn on the top left screw then one turn on the bottom left screw until they are completely loosened.

**Tip:** You might need to loosen the left two screws with a flathead screwdriver.



7. Grasp the thumbscrews and pull the LED board straight forward out of the casing.



**WARNING!** Use caution when removing the LED board. The LED might be hot to the touch after the board is removed.

A | Maintaining the Instrument



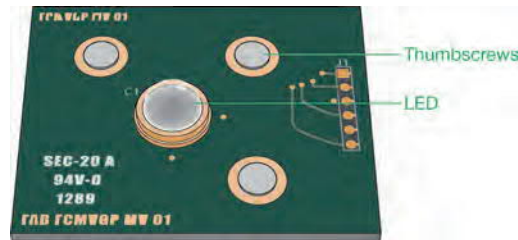
The following image shows the LED housing without the LED board.



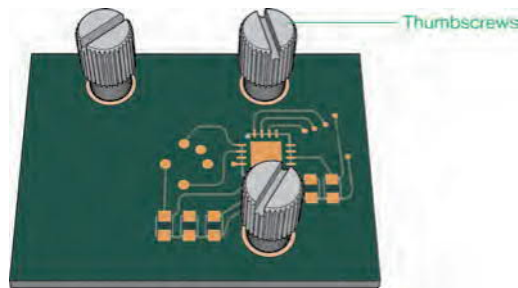
8. Dispose of the used LED in an appropriate waste receptacle.
9. Locate the new LED and remove it from its packing material.

## The Detectors

### Front of LED Board



### Back of LED Board



10. Align the thumbscrews of the replacement LED with the holes on the housing and carefully insert the LED into the casing.
11. Tighten the three thumbscrews to secure the lamp into the casing.
12. Slide the door to the LED casing into place until the latch secures.
13. Reconnect the tubing lines to the top and bottom of the UV cell.
14. Reconnect the tubing lines to the conductivity monitor.
15. Restart the NGC instrument.

A | Maintaining the Instrument

### Resetting the Single-Wavelength Lamp Time Details

The system tracks the lamp usage and displays the details on the Detector tab in the System Information dialog box in ChromLab.

After you change the single-wavelength lamps, you must reset the lamp time details in the system so that the details are current.

#### To reset single wave-length lamp time details

1. Start ChromLab.
2. Do one of the following:
  - On the ChromLab computer, from the System Control tab open File > System Information and select the Detector tab.
  - On the touch screen, open System Information from the menu and select the Detector tab.
3. Click Reset Lamps Time.
4. Restart the NGC instrument.

The values for lamp time hours for the single-wavelength UV lamps reset to 0.0 hr.

## Replacing the Multi-Wavelength UV/Vis Detector Lamps

This section explains how to replace the deuterium lamp or tungsten lamp inside the multi-wavelength UV/Vis detector. The replacement lamp unit includes the lamp, cable connector, and plug. The lamp is replaced as a unit.



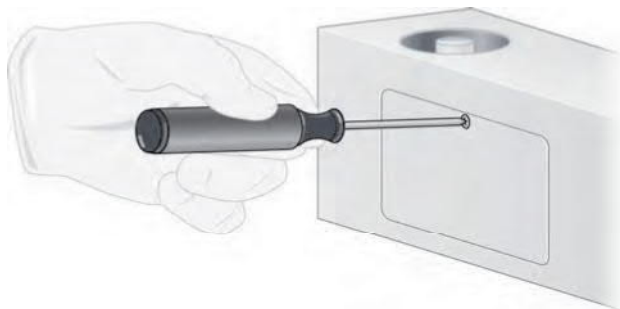
**Caution:** It is strongly suggested that you wear gloves when you replace the lamps. Do not touch the lamp glass with bare hands, as oils from your skin will degrade the lamp over time.

### To replace the multi-wavelength UV/Vis lamps

1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. Disconnect the tubing lines from the top and bottom of the UV cell.
3. Disconnect the tubing lines from the conductivity monitor.
4. Remove the multi-wavelength UV/Vis detector module from the instrument.

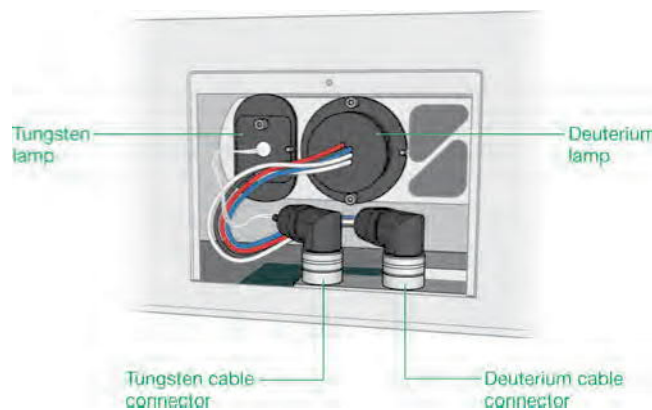
See [Replacing or Repositioning Modules on the NGC Instruments on page 233](#) for information about removing a module.

5. Using a screwdriver, loosen the screw and remove the door on the left side of the module.



A | Maintaining the Instrument

The deuterium and tungsten lamps are both accessible.



**Tip:** You might need to unscrew the cable connector for the tungsten lamp to access the collar to the cable connector for the deuterium lamp.

The Detectors

6. Remove the lamp:

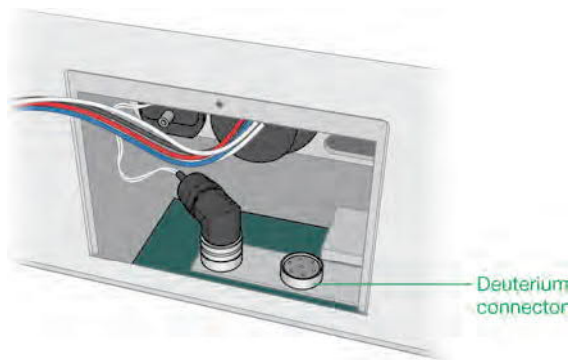


**WARNING!** Use caution when removing the lamps. The lamps might be hot to the touch after the module is removed.

- a. Using your fingers, loosen the collar on the cable plug.

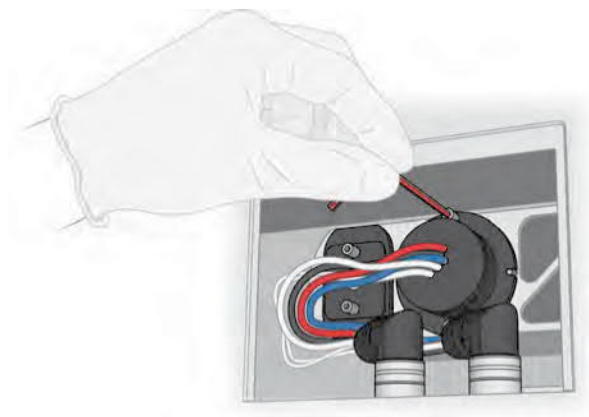


- b. Pull the plug upward to disconnect the cable.



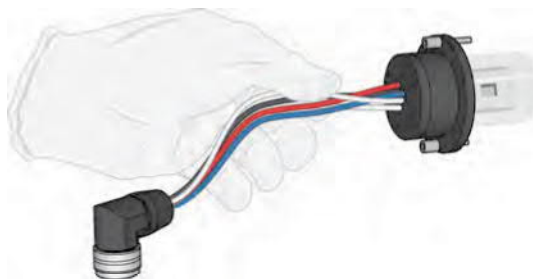
A | Maintaining the Instrument

- c. With a 2.5 mm hex key, remove the screws on the top and bottom of the lamp casing.



- d. Gently pull the lamp casing and lamp out of the socket.

The following image shows a completely disassembled deuterium lamp unit.



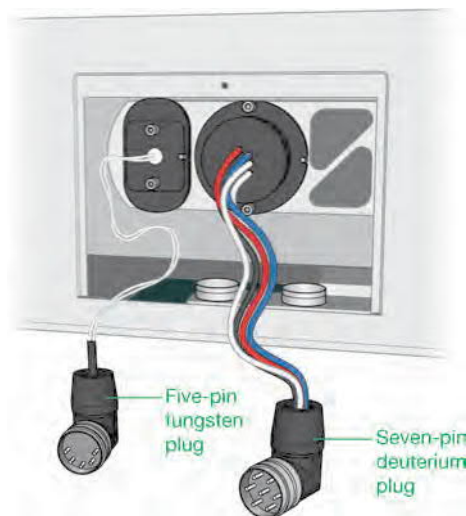
- e. Dispose of the used lamp in an appropriate waste receptacle.
7. Locate the replacement lamp and remove it from its packaging.
8. Carefully insert the replacement lamp fixture into the socket.
9. Align the screw holes on the lamp unit with the screw holes in the case.
10. Using the 2.5 mm hex key, tighten the screws to secure the lamp unit.



## The Detectors

11. Insert the cable plug and tighten the collar.

**Tip:** The deuterium lamp plug has seven connector pins, the tungsten lamp has five.



12. Replace the access door and tighten the screw with a Phillips screwdriver.
13. Slide the multi-wavelength UV/Vis module into its bay and fasten it in place by tightening the two screws.
14. Reconnect the tubing lines to the top and bottom of the UV cell.
15. Reconnect the tubing lines to the conductivity monitor.
16. Restart the NGC instrument.

**Note:** The multi-wavelength UV/Vis detector will go through an automated calibration routine when the system is restarted.

A | Maintaining the Instrument

## Replacing the Conductivity Monitor

The images in this section show the conductivity monitor on the single-wavelength UV detector module. Though the position of the conductivity monitor differs on the multi-wavelength UV/Vis module, the steps to replace the conductivity monitor are the same.

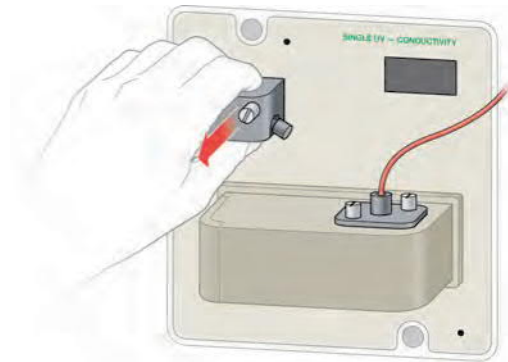
### To replace the conductivity monitor

1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. Disconnect the tubing lines from the conductivity monitor.
3. Loosen the two thumbscrews on the front of the detector.



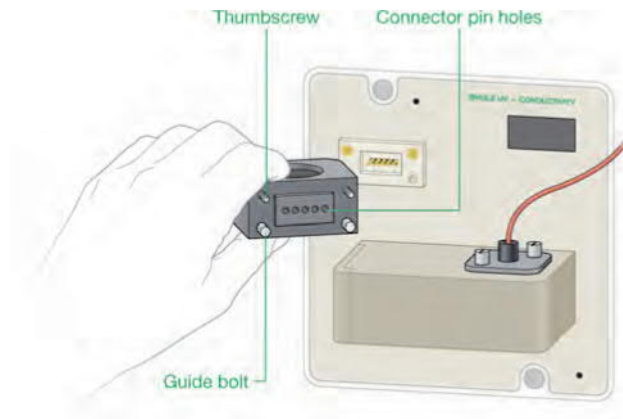
## The Detectors

4. Firmly grasp the detector and pull it toward you to detach it.



5. Dispose of the detector in an appropriate waste receptacle.
6. Locate the replacement detector and remove it from its packaging.
7. Align the two thumbscrews with the screw holes and the pin holes to the pins on the instrument.

**Tip:** The thumbscrews are on the top of the detector. There are two guide bolts on the bottom of the detector.



**Caution:** Do not bend or break the connector pins.

A | Maintaining the Instrument

8. Gently push the detector onto the connector pins on the instrument.
9. Tighten the thumbscrews to secure the detector in place.
10. Reconnect the tubing lines to the conductivity monitor.
11. Restart the NGC instrument.

**Note:** The conductivity monitor will go through an automated calibration routine when you restart the system.

## pH Probe

### Storing the pH Electrode

When not in use, store the pH electrode in storage solution. See Table 15 on page 159 for recommended storage solutions.

**Tip:** Set the pH valve to Bypass mode until it is needed. This ensures the pH electrode remains in storage.

#### To store the pH electrode

1. Start ChromLab software.
2. Choose Tools > Calibrate to open the Calibration dialog box.
3. Select pH on the Calibrate dropdown list.
4. Press Start to set the pH monitor to Calibration mode.
5. On the pH valve, inject approximately 10 ml of pH electrode storage solution through the Cal In port.
6. Click Close to close the Calibration dialog box.

**Note:** You might see a ChromLab message warning you about interrupting calibration. You can safely ignore this message. Any previous calibration performed on the pH valve is saved.

### Cleaning the pH Electrode

#### To remove soluble contaminants

- Sequentially immerse the electrode in the following solutions for 1 min each:
  - 0.1 M HCl
  - Distilled H<sub>2</sub>O
  - 0.1 M NaOH
  - Distilled H<sub>2</sub>O
  - 0.1 M HCl

A | Maintaining the Instrument

**To remove lipophilic organic contaminants**

- ▶ Immerse the electrode in an organic solvent or a liquid detergent, for example
  - Bio-Rad cleaning concentrate, catalog #161-0722
  - 2% Contrad, catalog #176-4118

**Replacing the pH Probe**

The replacement pH probe is packaged in storage solution to protect it during shipping.

**To replace the pH probe**

1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. Loosen the nut on the DNS cable and disconnect it from the DNS connector on the front of the pH module.



pH Probe

3. Loosen the black collar on the pH probe.
4. To remove the pH probe, lift the probe out of the pH flow cell.  
Dispose of the probe in an appropriate waste receptacle.
5. Add a small amount of water (2 ml) to the pH flow cell.
6. Locate the replacement pH probe and remove it from the storage solution.
7. Ensure that the pH probe cord is threaded through the collar.
8. Inspect the probe to determine if the air bubble in the stem has moved into the bulb area.

**Tip:** If bubbles are visible in the bulb area, hold the electrode by the top cap and shake it downward to move the bubbles into the stem.

9. Carefully remove the plastic cap from the pH probe and ensure that the O-ring is in place on the body.



**Caution:** Use caution when removing the plastic cap so as not to damage the glass probe.

10. Insert the probe into the top of the pH flow cell.
11. Slide the collar over the pH probe onto the pH valve and hand-tighten the collar until it is snug.



**Caution:** Do not overtighten the collar. Overtightening will break the glass pH probe.

12. Connect the pH probe cable to the DNS connector on the pH valve module.
13. Restart the NGC instrument.
14. Calibrate the pH monitor. See [Calibrating pH on page 150](#) for more information.

## Other Components

### Attaching an Expansion Tier to the NGC Instrument



**WARNING!** Disconnect power to the NGC instrument before attaching an expansion tier. Do not attempt to service any component on the NGC instrument unless noted in this manual. Contact Bio-Rad for service requests.

To attach the connector cable, you will need access to the back of the NGC instrument. If necessary, pull the NGC instrument away from the wall and rotate the instrument to gain access.

**Important:** If you are adding a fourth expansion tier, you must attach it to an already attached third tier. The third and fourth tiers are not interchangeable. Ensure that the third tier is installed on the NGC instrument before attaching the fourth tier.

#### To attach an expansion tier to the NGC instrument

1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. Remove all tubing lines to sample and buffer bottles and remove any bottles from the buffer tray.
3. Lift the top off the NGC instrument and place it on the lab bench.



#### Other Components



**Tip:** The buffer tray can remain inside the top.

4. Locate the package that contains the expansion tier and 52" (1.32 m) connector cable.

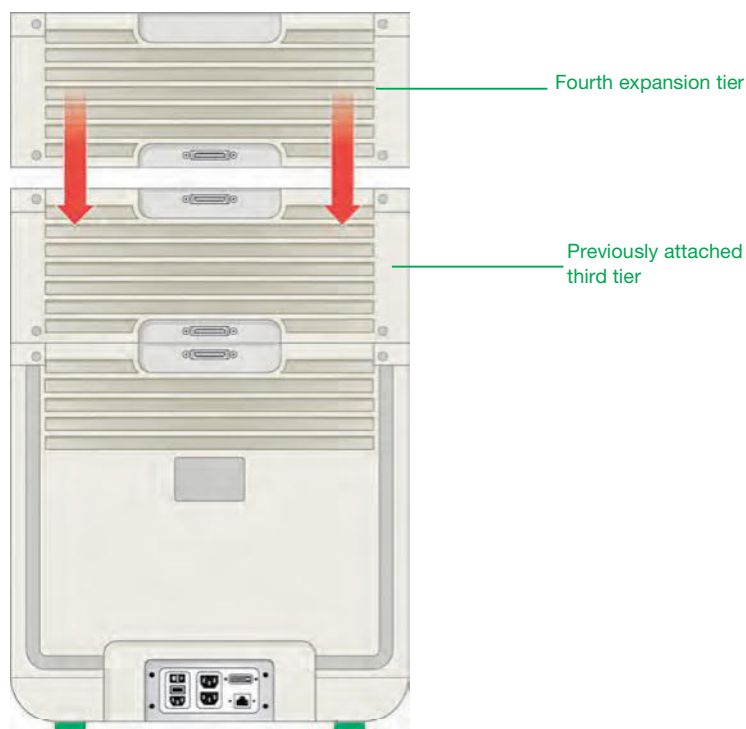
**Important:** The cables that ship with third and fourth tiers are not interchangeable. You must use the cable that ships with the expansion tier. Inserting a third tier cable into the fourth tier connector ports will damage the cable and the ports.

- The catalog number for the 25" (63.5 cm) second-to-third tier connector cable is #100-24878.
- The catalog number for the 52" (1.32 m) third-to-fourth tier connector cable is #100-24892.

5. Carefully remove the tier from its packaging material.
6. Place the expansion tier on top of the already installed tier.

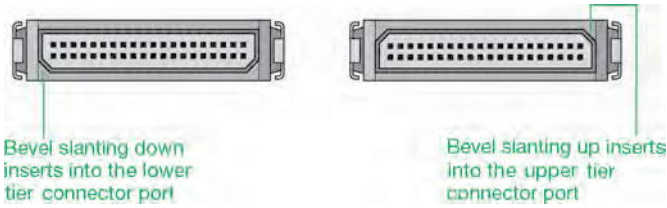
**Tip:** Although the images in this section show how to attach the fourth expansion tier to an already installed third tier, the procedure for attaching a third tier to a second tier is the same. These images are examples.

A | Maintaining the Instrument

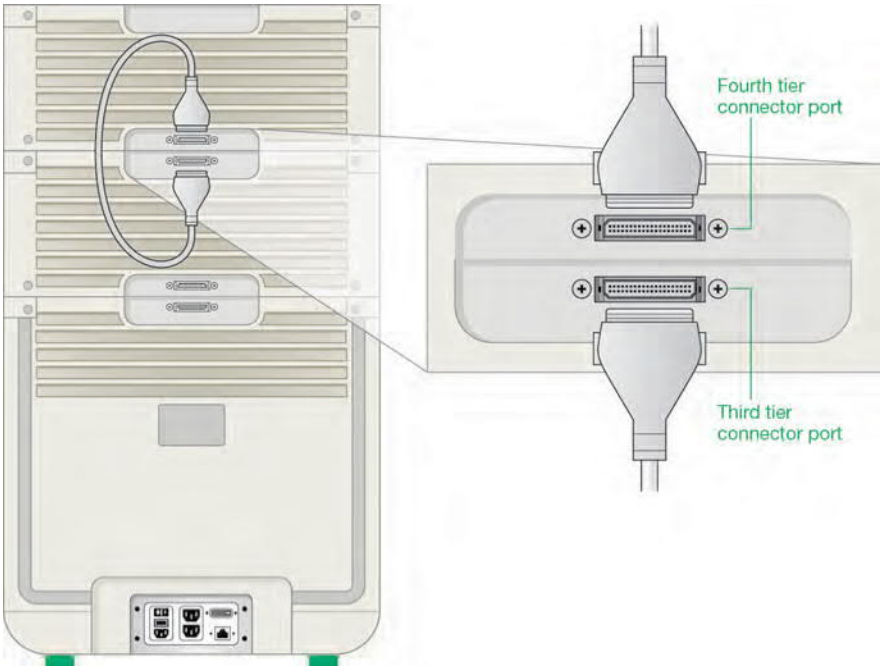


7. Locate the connector cable that ships with the expansion tier.
8. View the connector ends. Each end is beveled. The direction of the bevel determines the tier into which to insert the connector:
  - The end with the bevel slanting up inserts into the upper tier's connector port.
  - The end with the bevel slanting down inserts into the lower tier's connector port.

Other Components

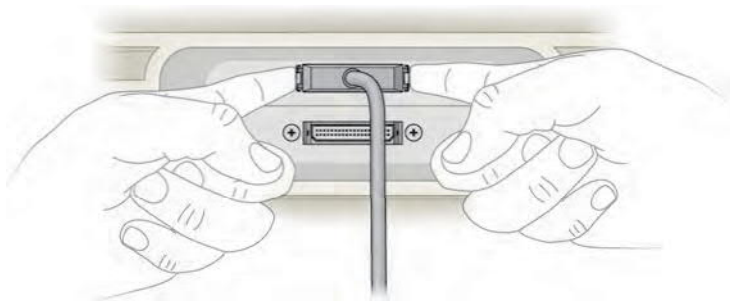


For example:

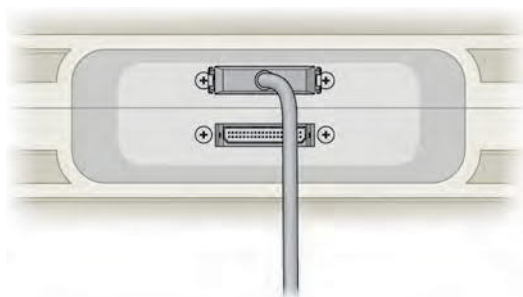


A | Maintaining the Instrument

9. Firmly press the clips inward and insert the appropriate connector into the upper tier's connector port.

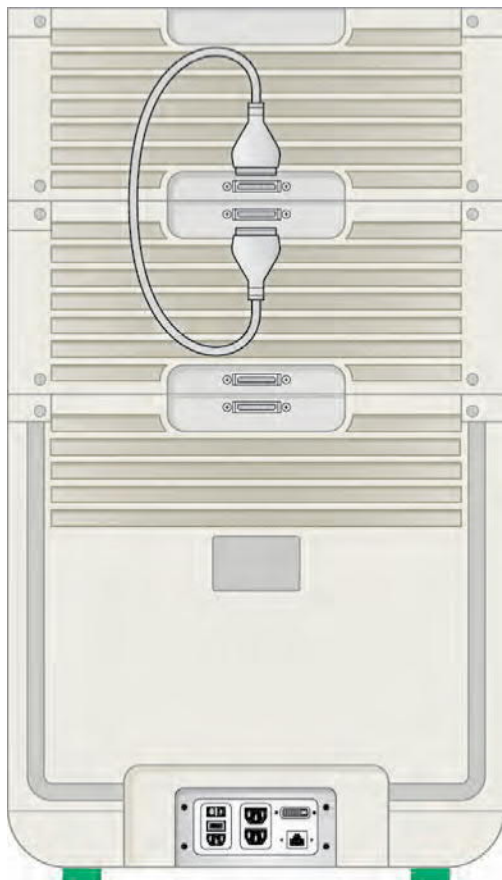


**Tip:** You hear a click when the connector is properly seated.



Other Components

10. Insert the other connector into the lower tier's connector port.



11. Place the top, with the buffer tray, on top of the NGC instrument and place the buffer bottles into the buffer tray.
12. Insert tubing lines into the sample and buffer bottles.

A | Maintaining the Instrument

13. Perform the following tasks:

Task:	Refer to the section:
Insert modules into the new tier	<a href="#">Replacing or Repositioning Modules on the NGC Instruments on page 233</a>
Plumb the system	<a href="#">Plumbing NGC Systems on page 270</a>
Start the instrument	<a href="#">Starting the NGC Instrument on page 119</a>
Prime the system	<a href="#">Priming and Purging the Systems on page 123</a>
Calibrate the system	<a href="#">Calibrating the NGC Instrument on page 150</a>

## Replacing or Repositioning Modules on the NGC Instruments



**WARNING!** Disconnect power to the NGC instrument before removing or repositioning any module. Do not attempt to service any component on the NGC instrument unless noted in this manual. Contact Bio-Rad for service requests.



**WARNING!** To reduce the chance of liquid seeping into the instrument, all open bays must be filled with the NGC Blank module (catalog #788-4005). The NGC instrument will not operate if it detects a slot without a module inserted.

### To replace or reposition modules on the NGC instruments

1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. If necessary, disconnect all tubing lines to and from the module that you plan to replace or reposition.
3. Loosen the captive screws on the front of the installed module.
4. Firmly grasp both screws on the module and pull it forward out of its bay.

A | Maintaining the Instrument

The following image shows an empty bay.



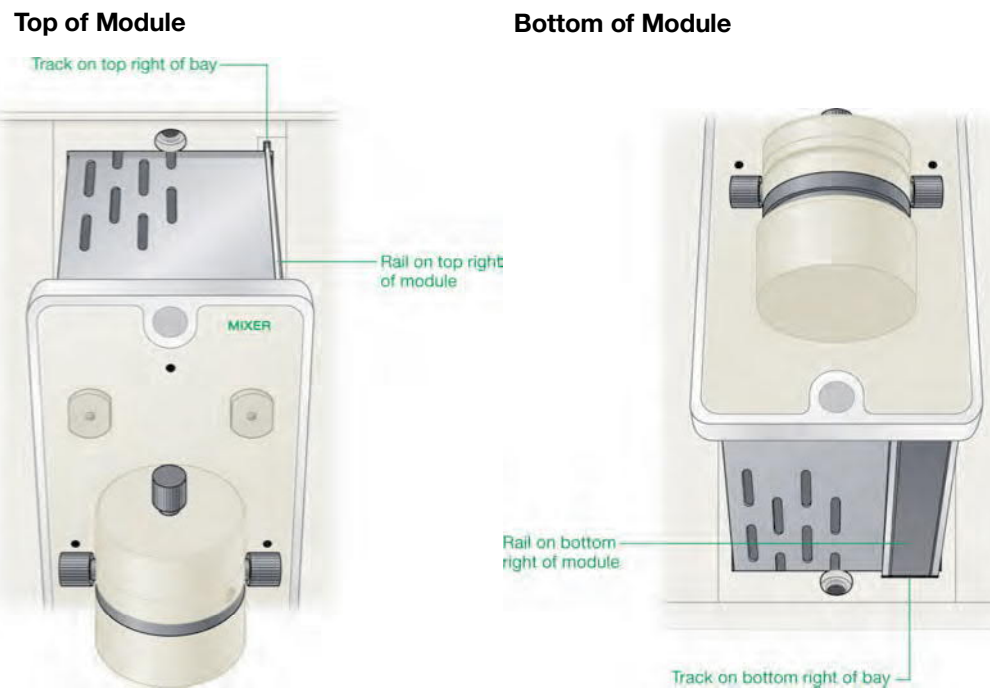
5. Store the module and the screws in a safe place for future use.  
**Tip:** If you received a replacement module from Bio-Rad, use the packaging provided with your shipment to return the damaged module to Bio-Rad.
6. (Optional) Convert the bay to single wide or double wide.  
See [Converting Bays to Fit Modules on page 237](#).
7. Locate the module that you plan to install and remove it from its packaging.



Other Components

8. The frame of the bay has tracks on the top and bottom of the right side. The module has guide rails on the top and bottom right side.

Align the rails on the module with the tracks in the bay to properly guide it into position.



9. Place the module into the open bay and gently push it in as far as it will go.

**Note:** Each module has an alignment pin on the back to ensure that it aligns correctly with the main communication board.

10. Ensure that the screw holes on the module align with the screw holes on the bay.
11. Insert the screws that shipped with the module into the screw holes.
12. Tighten the screws to secure the module.

A | Maintaining the Instrument

13. Perform the following tasks:

Task:	Refer to the section:
Plumb the system	<a href="#">Plumbing NGC Systems on page 270</a>
Start the instrument	<a href="#">Starting the NGC Instrument on page 119</a>
Prime the system	<a href="#">Priming and Purging the Systems on page 123</a>
Calibrate the system	<a href="#">Calibrating the NGC Instrument on page 150</a>

Other Components

### Converting Bays to Fit Modules

Some modules fit into single-wide bays while others require double-wide bays (such as the system and sample pump modules and the UV and UV/Vis detector modules). Bays can be converted from one size to the other by adding or removing the center divider.

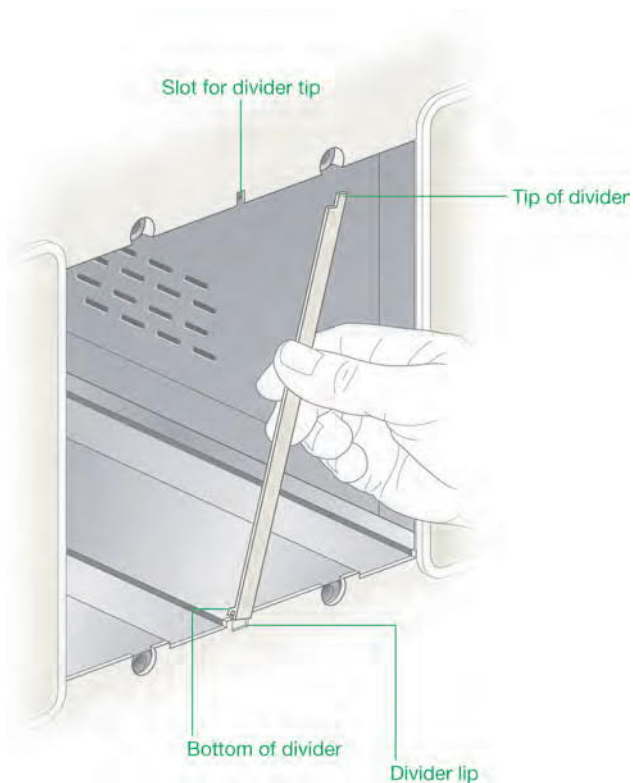
The following image shows two adjacent, empty, single-wide bays.



A | Maintaining the Instrument

**To convert a single-wide bay to a double-wide bay**

1. Complete steps 1–5 in the section **To replace or reposition modules on the NGC instruments.**
2. Gently lift the divider upward off of the lip to unhook it and then pull it out of the instrument.



3. Store the divider in a safe place for later use.
4. Complete steps 7–12 in the section **To replace or reposition modules on the NGC instruments.**

## Other Components

### **To convert a double-wide bay to a single-wide bay**

1. Locate a divider.
2. Complete steps 1–5 in the section [To replace or reposition modules on the NGC instruments on page 233](#).
3. Insert the top of the divider into its slot.
4. Gently bend the divider and slide the bottom of the divider up onto the lip.
5. Complete steps 7–12 in the section [To replace or reposition modules on the NGC instruments](#).



## E Regulatory Information

The NGC instrument has been tested and found to be in compliance with all applicable requirements of the following safety and electromagnetic compliance standards. The NGC instrument is labeled with the following compliance marks.

### Safety Compliance

CE Mark:

- EN61010-1 Electrical Equipment for Measurement, Control, and Laboratory Use
- IEC 61010-1 Safety Requirements for Measurement, Control, and Laboratory Use, Part 1: General Requirements

cTUVus Mark:

- UL STD No. 61010-1 Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements
- CAN/CSA C22.2 No. 61010-1-12 Safety Requirements for Measurement, Control, and Laboratory Use, Part 1: General Requirements (includes Amendment 1)

Products with these safety compliance marks are safe to use when operated in accordance with the instruction manual. This does not extend to accessories with no marks, even when used with this unit.



**Bio-Rad  
Laboratories, Inc.**

Life Science  
Group

**Web site** [bio-rad.com](http://bio-rad.com) **USA** 1 800 424 6723 **Australia** 61 2 9914 2800 **Austria** 43 01 877 89019 **Belgium** 32 03 710 53 00  
**Brazil** 55 11 3065 7550 **Canada** 1 905 364 3435 **China** 86 21 6169 8500 **Czech Republic** 36 01 459 6192  
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**Japan** 81 3 6361 7000 **Korea** 82 2 3473 4460 **Mexico** 52 555 488 7670 **The Netherlands** 310 318 540 666  
**New Zealand** 64 9 415 2280 **Norway** 47 0 233 841 30 **Poland** 36 01 459 6191 **Portugal** 351 21 4727717  
**Russia** 7 495 721 14 04 **Singapore** 65 6415 3188 **South Africa** 36 01 459 6193 **Spain** 34 091 49 06 580  
**Sweden** 46 08 555 127 00 **Switzerland** 41 0617 17 9555 **Taiwan** 886 2 2578 7189 **Thailand** 66 2 651 8311  
**United Arab Emirates** 971 4 8187300 **United Kingdom** 44 01923 47 1301



# **EXHIBIT 6**

**FILED UNDER SEAL**





























# **EXHIBIT 7**

**FILED UNDER SEAL**

7/9/2020

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Farah Mavandadi

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

_____	)	
CYTIVA SWEDEN AB and	)	
GLOBAL LIFE SCIENCES	)	
SOLUTIONS USA LLC,	)	
	)	
Plaintiffs,	)	
	)	
-vs-	)	
	)	C.A. No. 18-1899-CFC
BIO-RAD LABORATORIES,	)	CONSOLIDATED
INC.,	)	
	)	
Defendant.	)	
_____	)	

\*\*HIGHLY CONFIDENTIAL - TECHNICAL\*\*  
\*\*ATTORNEY'S EYES ONLY\*\*

VIDEOTAPED DEPOSITION  
TAKEN REMOTELY VIA ZOOM VIDEOCONFERENCE  
OF  
FARAH MAVANDADI

523 JETER STREET  
REDWOOD CITY, CALIFORNIA 94062  
JULY 9, 2020  
9:02 A.M.

REPORTED BY:  
DEBRA SAPIO LYONS, RDR, CRR, CRC, CCR, CLR, CPE

\_\_\_\_\_  
DIGITAL EVIDENCE GROUP  
1730 M Street, NW, Suite 812  
Washington, D.C. 20036  
(202) 232-0646

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1

July 9, 2020

2

Videotaped deposition, taken remotely via

3

Zoom videoconference, of Farah Mavandadi,

4

located at 523 Jeter Street, Redwood City,

5

California 94062, reported remotely via Zoom

6

Videoconference by Debra Sapio Lyons, a

7

Registered Diplomat Reporter, a Certified

8

Realtime Reporter, a Certified Realtime

9

Captioner, a Certified LiveNote Reporter, an

10

Approved Reporter of the United States

11

District Court for the Eastern District of

12

Pennsylvania, a Certified Court Reporter of

13

the State of New Jersey, and a Notary Public

14

of the State of Delaware.

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16

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22

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Page 3

1 (All Counsel and Participants present via Zoom  
2 videoconference.)

3  
4 APPEARANCES:

5  
6 ARNOLD & PORTER KAYE SCHOLER LLP  
BY: JEFFREY A. MILLER, ESQUIRE  
7 3000 El Camino Real Five Palo Alto  
Square, Suite 500  
8 Palo Alto, California 94306-3807  
650.319.4538  
9 jeffrey.miller@arnoldporter.com  
10 Attorneys for Plaintiffs  
11

12 QUINN EMANUEL URQUHART & SULLIVAN, LLP  
BY: FELIPE CORREDOR, ESQUIRE  
13 50 California Street, 22nd Floor  
San Francisco, California 94111  
14 415.875.6448  
felipecorredor@quinnemanuel.com  
15 Attorneys for Defendant  
16

17 ALSO PRESENT:

18  
19 LAURA LAVERNIA, SUMMER ASSOCIATE  
ARNOLD & PORTER  
20 HENRY MARTE, VIDEOGRAPHER/DOCUMENT TECH  
21 DIGITAL EVIDENCE GROUP  
22



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1	I N D E X	
2	WITNESS	PAGE
3	Farah Mavandadi	
4	BY MR. MILLER	15
5	E X H I B I T S	
6	NUMBER DESCRIPTION	PAGE
7	Exhibit 73, Plaintiffs' Notice of Deposition and Subpoena to Non-Party Farah Mavandadi	20
8		
9		
10	Exhibit 74, e-mail correspondence bearing Bates numbers BRGEDEL000300236 through BRGEDEL000300237	34
11		
12		
13	Exhibit 75, multipage document entitled [REDACTED] [REDACTED] [REDACTED] bearing the Bates numbers BRGE00065106 through BRGE00065161	101
14		
15		
16		
17	Exhibit 76, multipage document entitled NGC™ Medium Pressure Chromatography Systems bearing Bates numbers BRGEDEL000246325 through BRGEDEL000246360	126
18		
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21	Exhibit 77, e-mail correspondence bearing the Bates number BRGEDEL000310414	146
22		

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1	E X H I B I T S		
2	NUMBER	DESCRIPTION	PAGE
3	Exhibit 78,	e-mail correspondence	157
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4	BRGEDEL000317118 through		
	BRGEDEL000317119		
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6	Exhibit 79,	e-mail correspondence	183
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7	BRGEDEL000285516 through		
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9	Exhibit 80,	e-mail correspondence	189
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10	BRGEDEL000454986 through		
	BRGEDEL000454987		
11			
12	Exhibit 81,	e-mail correspondence	199
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13	BRGEDEL000325922		
14			
15	Exhibit 82,	a multipage document	199
	bearing Bates numbers		
16	BRGEDEL000325923 through		
	BRGEDEL000325925		
17			
18	Exhibit 83,	one-page document	209
	entitled Calendar Entry Meeting		
19	bearing Bates number BRGEDEL000346234		
20			
21			
22			

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1	E X H I B I T S		
2	NUMBER	DESCRIPTION	PAGE
3	Exhibit 84,	e-mail correspondence	214
		bearing Bates numbers	
4		BRGEDEL000436636 through	
		BRGEDEL000436642	
5			
6	Exhibit 85,	multipage document	216
		entitled TTT AKTA™ pure, Advanced	
7		configurations bearing Bates numbers	
		BRGEDEL000436643 through	
8		BRGEDEL000436664	
9			
10	Exhibit 86,	e-mail correspondence	219
		bearing Bates numbers	
11		BRGEDEL000175721 through	
		BRGEDEL000175724	
12			
13	Exhibit 87,	e-mail correspondence	222
		bearing the Bates number	
14		BRGEDEL000316529	
15			
16	Exhibit 88,	e-mail correspondence	227
17		bearing Bates number BRGEDEL000316533	
18			
19	Exhibit 89,	multipage document	234
		entitled [REDACTED] bearing	
20		Bates numbers BRGEDEL000448581	
21		through BRGEDEL000448613	
22			

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1	E X H I B I T S		
2	NUMBER	DESCRIPTION	PAGE
3	Exhibit 90,	multipage document	238
		entitled AKTA pure Protein	
4		Purification your way bearing Bates	
		numbers BRGEDEL000261366 through	
5		BRGEDEL000261396	
6			
7	Exhibit 91,	multipage document	242
		entitled AKTA™ pure Protein	
8		purification your way bearing Bates	
		numbers BRGEDEL000263336 through	
9		BRGEDEL000263377	
10			
11	Exhibit 92,	multipage document	244
		entitled TTT AKTA™ PURE System	
12		Introduction bearing Bates numbers	
		BRGEDEL000265458 through	
13		BRGEDEL000265494	
14			
15	Exhibit 93,	multipage document	245
		entitled TTT AKTA™ pure UNICORN™ 6.3	
16		Your interface to AXCELLENCE bearing	
		the Bates numbers BRGEDEL000439607	
17		through BRGEDEL000439643	
18			
19	Exhibit 94,	multipage document	246
		entitled AKTA™ pure Protein	
20		purification your way bearing the	
21		Bates numbers BRGEDEL000440176	
22		through BRGEDEL000440229	

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1	E X H I B I T S		
2	NUMBER	DESCRIPTION	PAGE
3	Exhibit 95,	multipage document	247
4		entitled Service Products bearing the	
5		Bates numbers BRGEDEL000441677	
6		through BRGEDEL000441697	
7	Exhibit 96,	multipage document	248
8		entitled Life Sciences Validation	
9		Services AKTA™ pure Validation	
10		Services bearing Bates numbers	
11		BRGEDEL000442435 through	
12		BRGEDEL000442452	
13	Exhibit 97,	multipage document	249
14		entitled TTT AKTA™ pure Protein	
15		purification using AKTA™ pure	
16		Additional automation bearing Bates	
17		numbers BRGEDEL000442885 through	
18		BRGEDEL000442924	
19	Exhibit 98,	two-page document	250
20		entitled AKTA™ pure, There's an AKTA™	
21		pure for everyone., bearing the Bates	
22		numbers BRGEDEL000262459 through	
		BRGEDEL000262460	

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1	PREVIOUSLY MARKED EXHIBITS		
	2 NUMBER	DESCRIPTION	PAGE
3	Exhibit Iovanni-3, multipage document		43
		entitled [REDACTED]	
		[REDACTED]	
		[REDACTED]	
5	bearing Bates numbers BRGE00006279		
	through BRGE00006301		
6			
7	Exhibit Iovanni-4, multipage document		65
		entitled [REDACTED]	
		[REDACTED]	
		[REDACTED] bearing Bates numbers	
9	BRGEDEL000288592 through		
	BRGEDEL000288623		
10			
11	Exhibit Iovanni-5, multipage document		70
		entitled [REDACTED]	
		[REDACTED]	
		[REDACTED] bearing Bates numbers	
13	BRGE00065053 through BRGE00065075		
14			
15	Exhibit Iovanni-6, multipage document		73
		entitled [REDACTED]	
		[REDACTED] bearing	
		Bates numbers BRGE00006302 through	
17	BRGE00006305		
18			
19	Exhibit Iovanni-7, one-page document		77
		entitled [REDACTED]	
		[REDACTED]	
		[REDACTED] bearing Bates number	
22	BRGE00065076		

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1	PREVIOUSLY MARKED EXHIBITS		
	2 NUMBER	DESCRIPTION	PAGE
3	Exhibit Iovanni-10, multipage		80
		document entitled [REDACTED]	
		[REDACTED]	
		[REDACTED] bearing Bates numbers	
5		BRGE00006470 through BRGE00006479	
6			
7	Exhibit Iovanni-16, multipage		81
		document entitled [REDACTED]	
		[REDACTED]	
		[REDACTED] bearing Bates numbers	
9		BRGE00065080 through BRGE00065089	
10			
11	Exhibit Iovanni-27, multipage		85
		document entitled [REDACTED]	
		[REDACTED]	
		[REDACTED] bearing Bates	
13		numbers BRGE00016955 through	
		BRGE00016987	
14			
15	Exhibit Iovanni-25, e-mail		92
		correspondence bearing Bates numbers	
16		BRGEDEL000341332 through	
		BRGEDEL000341334	
17			
18	Exhibit Iovanni-30, multipage		96
		document entitled [REDACTED]	
		[REDACTED]	
		[REDACTED] bearing Bates numbers	
20		BRGEDEL000014644 through	
21		BRGEDEL000014657	
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1	PREVIOUSLY MARKED EXHIBITS		
2	NUMBER	DESCRIPTION	PAGE
3	Exhibit Iovanni-29,	multipage	111
		document bearing Bates numbers	
4		BRGEDEL000401625 through	
		BRGEDEL000401658	
5			
6	Exhibit Iovanni-31,	multipage	116
		document entitled [REDACTED]	
7	[REDACTED]		
		bearing Bates numbers	
8		BRGEDEL000401312 through	
9		BRGEDEL000401330	
10			
11	Exhibit Iovanni-33,	multipage	122
		document bearing Bates numbers	
12		BRGE00034403 through BRGE00034417	
13			
14	Exhibit Iovanni-35,	e-mail	171
		correspondence bearing Bates numbers	
15		BRGEDEL000300620	
16			
17	Exhibit Iovanni-36	multipage document	171
		entitled [REDACTED]	
18	[REDACTED]	bearing Bates number	
		BRGEDEL000300621 through	
19		BRGEDEL000300645	
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1	PREVIOUSLY MARKED EXHIBITS		
2	NUMBER	DESCRIPTION	PAGE
3	Exhibit Iovanni-37, e-mail		192
		correspondence bearing Bates numbers	
4		BRGEDEL000421000 through	
		BRGEDEL000421001	
5			
6	Exhibit Iovanni-40, e-mail		194
		correspondence bearing Bates numbers	
7		BRGEDEL000201040 through	
8		BRGEDEL000201041	
9			
10	Exhibit Iovanni-39, e-mail		202
		correspondence bearing Bates numbers	
11		BRGEDEL000393786 through	
12		BRGEDEL000393789	
13			
14			
15			
16			
17			
18			
19			
20			
21	(Reporter's Note: Exhibits were digitally		
22	marked by Document Technician.)		

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1 THE VIDEOGRAPHER: Okay. We are  
2 now on the record. My name is Henry  
3 Marte, I'm a videographer on behalf of  
4 Digital Evidence Group. Today's date is  
5 July 9th, 2020 and the time is 9:02 a.m.

6 This deposition is being held via  
7 remote Zoom in the matter of Cytiva  
8 Sweden AB, et al., versus Bio-Rad  
9 Laboratories, Inc. The deponent today  
10 is Dr. Farah Mavandadi. All appearances  
11 are noted on the stenographic record.

12 Will the court reporter please  
13 administer the oath to the witness?

14 THE REPORTER: Counsel, before  
15 swearing in the witness I have a  
16 statement to put on the record.

17 The attorneys participating in  
18 this deposition acknowledge that due to  
19 the severity of COVID-19 and following  
20 the practice of social distancing, I am  
21 not physically present in the deposition  
22 room and I will be swearing in the

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1 witness and reporting this deposition  
2 remotely.

3 Do all parties stipulate to the  
4 validity of this remote swearing and  
5 remote reporting via video conference  
6 and that it will be admissible in the  
7 courtroom as if it had been taken  
8 following Rule 30 and other rules of the  
9 Federal Rules of Civil Procedures?

10 MR. MILLER: This is Jeffrey  
11 Miller for the Plaintiffs, we -- we  
12 agree.

13 MR. CORREDOR: Felipe Corredor  
14 for Defendant Bio-Rad, we agree as well.

15 - - -

16 FARAH MAVANDADI, having been  
17 first duly sworn, was examined and  
18 testified as follows:

19 - - -

20 THE REPORTER: Thank you.  
21 You may proceed.

22 MR. MILLER: Thank you.

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1 MR. CORREDOR: Objection.

2 BY MR. MILLER:

3 Q. -- is that correct?

4 MR. CORREDOR: Objection to the  
5 form.

6 THE WITNESS: That's what it  
7 appears to be.

8 Again, there were some elements,  
9 not everything we had thought about.

10 BY MR. MILLER:

11 Q. Could you go to BRGE65119,  
12 please?

13 A. I am there.

14 Q. At the very top there's a  
15 sentence that says, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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1 BY MR. MILLER:

2 Q. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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1

2

3

BY MR. MILLER:

4

5

Q. Was the AKTA avant a -- an  
automated liquid chromatography system?

6

7

MR. CORREDOR: Objection to the  
form.

8

THE WITNESS: I believe so.

9

BY MR. MILLER:

10

11

12

Q. Could you go to BRGE65132?  
Are you there? It's on the  
screen for you.

13

A. Yes, I'm there.

14

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CERTIFICATE

I, Debra Sapio Lyons, a Registered Diplomat Reporter, a Certified Realtime Reporter, a Certified Realtime Captioner, an Approved Reporter of the United States District Court for the Eastern District of Pennsylvania, a Certified Court Reporter for the State of New Jersey; and Notary Public do hereby certify:

That Farah Mavandadi, the witness whose deposition is hereinbefore set forth, appeared remotely via Zoom videoconference, was remotely sworn by me and that such deposition is a true record of the testimony given by such witness, to the best of my ability and thereafter reduced to typewriting under my direction.

I further certify that I am not related to any of the parties to this action by blood or marriage and that I am in no way interested in the outcome of the matter.

In witness whereof, I have hereunto set my hand this 23rd day of July, 2020.



DEBRA SAPIO LYONS  
CRR, RDR, CRC, CCR, CPE

# **EXHIBIT 10**

**FILED UNDER SEAL**





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1 July 7, 2020

2 Videotaped deposition, taken remotely via  
3 Zoom videoconference, of Wayne Carlisle Bland,  
4 located at 415 Capitol Way North, Olympia,  
5 Washington 98501, reported remotely via Zoom  
6 Videoconference by Debra Sapio Lyons, a  
7 Registered Diplomat Reporter, a Certified  
8 Realtime Reporter, a Certified Realtime  
9 Captioner, a Certified LiveNote Reporter, an  
10 Approved Reporter of the United States  
11 District Court for the Eastern District of  
12 Pennsylvania, a Certified Court Reporter of  
13 the State of New Jersey, and a Notary Public  
14 of the State of Delaware.

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Page 3

1 (All Counsel and Participants present via Zoom  
2 videoconference.)

3

4 APPEARANCES:

5

ARNOLD & PORTER KAYE SCHOLER LLP

BY: JEFFREY A. MILLER, ESQUIRE

6

3000 El Camino Real Five Palo Alto  
Square, Suite 500

7

Palo Alto, California 94306-3807  
650.319.4538

8

jeffrey.miller@arnoldporter.com  
Attorneys for Plaintiffs

9

10

QUINN EMANUEL URQUHART & SULLIVAN, LLP

BY: FELIPE CORREDOR, ESQUIRE

11

50 California Street, 22nd Floor  
San Francisco, California 94111

12

415.875.6448  
felipecorredor@quinnemanuel.com

13

Attorneys for Defendant

14

15

ALSO PRESENT:

16

17

JOHN CASSINGHAM, ESQUIRE

BIO-RAD LABORATORIES, INC.

18

HENRY MARTE, VIDEOGRAPHER/DOCUMENT TECH  
DIGITAL EVIDENCE GROUP

19

20

21

22

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1	I N D E X	
2	WITNESS	PAGE
3	Wayne Carlisle Bland	
4	BY MR. MILLER	11
5	E X H I B I T S	
6	NUMBER	DESCRIPTION
7	Exhibit 45, Plaintiff's Notice of	17
8	Deposition and Subpoena to Non-Party	
9	Wayne Bland	
10	Exhibit 46, a multipage document	94
	entitled [REDACTED]	
	[REDACTED] bearing Bates numbers	
	BRGEDEL000441628 through	
12	BRGEDEL000441653	
13		
14	Exhibit 47, a multipage document	102
	entitled Hardware Specification	
15	bearing Bates numbers BRGE00096078	
	through BRGE00096094	
16		
17	Exhibit 48, a multipage document	120
	entitled [REDACTED]	
	[REDACTED] bearing Bates number	
	BRGEDEL000001507 through	
19	BRGEDEL000001540	
20		
21		
22		

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1	E X H I B I T S		
2	NUMBER	DESCRIPTION	PAGE
3	Exhibit 49, a multipage document		122
	entitled [REDACTED]		
	[REDACTED] bearing Bates number		
	BRGEDEL000000972 through		
5	BRGEDEL000001007		
6			
7	Exhibit 50, a multipage document		126
	entitled Hardware Specification		
8	bearing Bates numbers		
	BRGEDEL000450595 through		
9	BRGEDEL000450610		
10			
11	Exhibit 51, a multipage document		135
	entitled [REDACTED]		
	[REDACTED] bearing		
	Bates number BRGEDEL000001234 through		
13	BRGEDEL000001260		
14			
15	Exhibit 52, a multipage document		137
	entitled [REDACTED]		
16	bearing Bates numbers		
	BRGEDEL000282551 through		
17	BRGEDEL000282564		
18			
19	Exhibit 53, a multipage document		149
	entitled [REDACTED]		
	[REDACTED] bearing		
21	the Bates numbers BRGEDEL000001650		
22	through BRGEDEL000001693		

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1	E X H I B I T S		
2	NUMBER	DESCRIPTION	PAGE
3	Exhibit 54,	a multipage document	157
	entitled	[REDACTED]	
4	bearing Bates numbers		
	BRGEDEL000281529 through		
5	BRGEDEL000281542		
6			
7	Exhibit 55,	a multipage document	164
	entitled	[REDACTED]	
8	[REDACTED]	bearing	
	Bates number BRGEDEL000001346 through		
9	BRGEDEL000001379		
10			
11	Exhibit 56,	a multipage document	168
	entitled Hardware Specification		
12	bearing Bates numbers		
	BRGEDEL000450743 through		
13	BRGEDEL000450757		
14			
15	Exhibit 57,	multipage document	172
	entitled	[REDACTED]	
16	[REDACTED]	bearing the	
	Bates Number BRGEDEL000001261 through		
17	BRGEDEL000001286		
18			
19	Exhibit 58,	a multipage document	174
	entitled Hardware Specification		
20	bearing the Bates Number		
21	BRGEDEL000451786 through		
22	BRGEDEL000451802		

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1	E X H I B I T S	
2	NUMBER	PAGE
3	Exhibit 59, a multipage document	179
	entitled [REDACTED]	
	[REDACTED] bearing the Bates	
	numbers BRGEDEL000001405 through	
5	BRGEDEL000001439	
6		
7	Exhibit 60, e-mail correspondence	184
	bearing Bates number BRGEDEL98220	
8		
9	Exhibit 61, multipage document	185
	entitled [REDACTED]	
	[REDACTED]	
	bearing Bates numbers	
11	BRGEDEL000098221 through	
	BRGEDEL000098242	
12		
13	Exhibit 62, multipage document	186
	entitled [REDACTED]	
	[REDACTED]	
	bearing Bates numbers	
15	BRGEDEL000098243 through	
	BRGEDEL000098262	
16		
17	Exhibit 63, multipage document	186
	entitled [REDACTED]	
	[REDACTED] bearing the Bates numbers	
	BRGEDEL000098263 through	
19	BRGEDEL000098270	
20		
21		
22		

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1	E X H I B I T S		
2	NUMBER	DESCRIPTION	PAGE
3	Exhibit 64,	multipage document	187
	entitled	[REDACTED]	
	[REDACTED]		
	[REDACTED]	bearing the Bates numbers	
5	BRGEDEL000098271	through	
	BRGEDEL000098314		
6			
7	PREVIOUSLY MARKED EXHIBITS		
8	NUMBER	DESCRIPTION	PAGE
9	Exhibit Iovanni-6,	a multipage	40
	document entitled	[REDACTED]	
	[REDACTED]		
	[REDACTED]	bearing Bates numbers	
11	BRGE00006302	through BRGE00006305	
12			
13	Exhibit Iovanni-30,	a multipage	54
	document entitled	[REDACTED]	
	[REDACTED]		
	[REDACTED]	bearing Bates numbers	
15	BRGEDEL000014644	through	
	BRGEDEL000014657		
16			
17	Exhibit Iovanni-10,	a multipage	57
	document entitled	[REDACTED]	
	[REDACTED]		
	[REDACTED]	, bearing Bates numbers	
19	BRGE00006470	through BRGE00006479	
20			
21			
22			



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1	PREVIOUSLY MARKED EXHIBITS		
2	NUMBER	DESCRIPTION	PAGE
3	Exhibit Iovanni-29,	a multipage	73
		document entitled Technical	
4		Specification bearing Bates number	
		BRGEDEL000401625 through	
5		BRGEDEL000401658	
6			
7	Exhibit Iovanni-44,	United States	196
		Patent No. 10,401,335	
8			
9	Exhibit Iovanni-35,	e-mail	209
		correspondence bearing Bates number	
10		BRGEDEL000300620	
11			
12	Exhibit Iovanni-36,	multipage	209
		document entitled [REDACTED]	
	[REDACTED]	bearing Bates	
		numbers BRGEDEL000300621 through	
14		BRGEDEL000300645	
15			
16	Exhibit Iovanni-39,	e-mail	217
		correspondence bearing Bates numbers	
17		BRGEDEL000393786 through	
		BRGEDEL000393789	
18			
19			
20			
21	(Reporter's Note: Exhibits were digitally		
22	marked by Document Technician.)		

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1 THE VIDEOGRAPHER: Okay. We are  
2 now on the record. My name is Henry  
3 Marte, videographer on behalf of Digital  
4 Evidence Group.

5 Today's date is July 7th, 2020  
6 and the time is 9:02 a.m. Pacific time.  
7 This is in the matter of GE Healthcare  
8 Bio-Sciences, AB et al., versus Bio-Rad  
9 Laboratories, Inc. The deponent today  
10 is Wayne Bland. All appearances are  
11 noted on the stenographic record.

12 Would the court reporter please  
13 administer the oath to the witness?

14 THE REPORTER: Counsel, before  
15 swearing in the witness, I have a  
16 statement to put on the record.

17 The attorneys participating  
18 this -- in this deposition acknowledge  
19 that due to the severity of COVID-19 and  
20 following the practice of social  
21 distancing, I am not physically present  
22 in the deposition room and that I will

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1 be swearing in the witness and reporting  
2 this deposition remotely.

3 Do all parties stipulate to the  
4 validity of this remote swearing and  
5 remote reporting via video conference,  
6 and that it will be admissible in the  
7 courtroom as if it had been taken  
8 following Rule 30 and other rules of the  
9 Federal Rules of Civil Procedures?

10 MR. MILLER: Jeffrey Miller, I  
11 agree.

12 MR. CORREDOR: Felipe Corredor  
13 for Defendant Bio-Rad, we agree as well.

14 WAYNE CARLISLE BLAND, having been  
15 first duly sworn, was examined and  
16 testified as follows:

17 THE REPORTER: Thank you.

18 You may proceed.

19 EXAMINATION

20 BY MR. MILLER:

21 Q. Good morning, Mr. Bland.

22 A. Good morning.

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1 had a -- let me start again.

2 Did each of the modules have a  
3 CPU on them?

4 A. They had -- they had -- yeah,  
5 we'll call it a CPU.

6 Q. [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

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Q. Uh-huh. Thank you.

And do you recall

approximately -- well, scratch that.

When the first -- when the



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1 Q. Yeah.

2 A. Okay. All right.

3 Q. Yeah. Let me make it clear so  
4 it -- we get a complete question.

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

A horizontal bar chart titled 'Percentage of respondents who believe that the government should take action to reduce greenhouse gas emissions'. The chart is divided into two main sections: 'Age' and 'Gender'. Each section contains bars for 'Total', 'Male', and 'Female' respondents. The x-axis represents the percentage, ranging from 0 to 100. The y-axis lists the categories: Age (Total, Male, Female) and Gender (Total, Male, Female). The bars are colored blue for 'Total', orange for 'Male', and green for 'Female'. The data shows that a majority of respondents across all categories believe the government should take action to reduce greenhouse gas emissions, with the highest percentages generally found in the 'Total' and 'Male' categories.

Category	Sub-category	Percentage (%)
Age	Total	85
	Male	80
	Female	85
Gender	Total	85
	Male	80
	Female	85

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1 BY MR. MILLER:

2 Q. If we could go to page

3 BRGEDEL40001642, which is Page 18 of Exhibit

4 29, and I'm looking -- looking at Row U. It

5 says, [REDACTED]

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1 Do you see that?

2 A. I do.

3 Q. [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

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1 BY MR. MILLER:

2 Q. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

MR. MILLER: Why don't we mark as  
the next exhibit, a document bearing the  
Bates number BRGE96078. This will be  
Exhibit 47.

Let me make it more clear. So  
we'll -- let's mark as Exhibit 47 the  
document bearing Bates number BRGE96078  
through BRGE96094.

Let us know when that gets there.

THE VIDEOGRAPHER: Give me --  
give me one second, all right?

Okay. So I have 96078. Is that  
what you're looking for?

MR. MILLER: BRGE, not BRGEDEL.

You don't have it?

THE VIDEOGRAPHER: Yeah. I don't  
see that number here.

MR. MILLER: Can we go off the  
record for a second?

MR. CORREDOR: Sure.

THE VIDEOGRAPHER: All right.



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1 go.

2 BY MR. MILLER:

3 Q. So this particular page of  
4 Exhibit 47 states "Product Description." Do  
5 you see that?

6 A. I do.

7 Q. And about halfway down the page  
8 there's two lines. One says, "Analytical  
9 range," and the other one says, "Preparative  
10 range." Do you see that?

11 A. I do.

12 Q. Do you know what the -- do you  
13 have an understanding as to what those  
14 specifications are referring to?

15 MR. CORREDOR: Objection, form.

16 THE WITNESS: Go ahead.

17 BY MR. MILLER:

18 Q. You can answer.

19 A. Okay.

20 Yes, in the chromatography field,  
21 and also in the scientific field, it's --  
22 these are types of analysis that are ran and

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1 one is more precise than the other.

2 Q. Further down there's a line that

3 states [as read]: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

15 [REDACTED]

[REDACTED]

[REDACTED]

18 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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14 BY MR. MILLER:

15 Q. Why don't we go to the next page  
16 of Exhibit 47 which is BRGEE96082.

17 A. Okay.

18 Q. And there I'm looking at the --

19

20 [REDACTED]. Do you see  
21 that?

22 A. I do.

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1 Q. I'm not so much interested in  
2 that, but the comment where it says

[illegible]

21 BY MR. MILLER:

22 Q. Let's go to Page 6, which is

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1 BRGE6083.

2 A. Okay.

3 Q. [REDACTED]

■

■

[REDACTED]

■

■

[REDACTED]

■

■

[REDACTED]

■

■

[REDACTED]

■

[REDACTED]

■

■

[REDACTED]

■

■

[REDACTED]

■

[REDACTED]

[REDACTED]

■

[REDACTED]

■

[REDACTED]

[REDACTED]

■

[REDACTED]

■

[REDACTED]

■

[REDACTED]

■

■

[REDACTED]

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[REDACTED]

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[REDACTED]

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[REDACTED]

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[REDACTED]

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[REDACTED]





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4

Q. Why don't we go to BRGEDEL450598?

5

A. Okay.

6

MR. MILLER: Henry, are you

7

there?

8

THE VIDEOGRAPHER: I am. I'm

9

just looking for the document.

10

MR. MILLER: Okay. Well, let's

11

keep going here.

12

BY MR. MILLER:

13

Q. ■

■

■

■

■

Do you see that?

18

MR. CORREDOR: Object to the

19

form.

20

THE WITNESS: Where are you at?

21

BY MR. MILLER:

22

Q. BRGEDEL450598, which is Page 4.

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1 A. Okay. Oh, right. Okay.

2 Q. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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16

17

18

19

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22

THE REPORTER: You'll need to

repeat your objection.

MR. CORREDOR: Object to the

form.

BY MR. MILLER:

Q. Can we go to BRGEDEL450601?

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1 A. Okay.

2 Q. The first -- or excuse me. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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1 you see that?

2 Mr. Bland, do you see what I'm  
3 looking at?

4 A. No, sorry. I was in the wrong  
5 one.

6 Yes, I do.

7 Q. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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1 Q. Yes.

2 A. Not yet.

3 THE VIDEOGRAPHER: Yeah, it's a  
4 -- it's a bit big, so it's still  
5 uploading.

6 THE WITNESS: Oh, okay.

7 THE VIDEOGRAPHER: Okay. Refresh  
8 now.

9 THE WITNESS: Okay.

10 BY MR. MILLER:

11 Q. Can you identify Exhibit 53 for  
12 us, please?

13 A. Yes, this is [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]





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22

MR. MILLER: Can we provide the  
witness with the -- with what's been  
previously marked as Exhibit 44, please.

(Exhibit Iovanni-44, United  
States Patent No. 10,401,335 was  
previously marked for identification.)

BY MR. MILLER:

Q. Can you identify Exhibit 44 for  
us, please?

A. I don't see it.

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1 Q. Oh.

2 THE VIDEOGRAPHER: So it's --  
3 it's up. It doesn't start with an "E"  
4 so...

5 MR. MILLER: Yeah, this is --

6 THE VIDEOGRAPHER: It's Iovanni  
7 Exhibit 44. You should --

8 THE WITNESS: Ah.

9 THE VIDEOGRAPHER: -- refresh  
10 your page.

11 THE WITNESS: No.

12 THE VIDEOGRAPHER: You got it?

13 THE WITNESS: Did you just upload  
14 it?

15 THE VIDEOGRAPHER: I did. Well,  
16 about ten seconds ago or more.

17 THE WITNESS: Oh, okay. I  
18 thought it was an older document. Oh,  
19 okay.

20 Okay. I have it up.

21 BY MR. MILLER:

22 Q. Can you identify Exhibit 44 for

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CERTIFICATE

I, Debra Sapio Lyons, a Registered  
Diplomat Reporter, a Certified Realtime  
Reporter, a Certified Realtime Captioner, an  
Approved Reporter of the United States  
District Court for the Eastern District of  
Pennsylvania, a Certified Court Reporter for  
the State of New Jersey; and Notary Public for  
the State of Delaware do hereby certify:

That Wayne Carlisle Bland, the witness  
whose deposition is hereinbefore set forth,  
was duly sworn by me and that such deposition  
is a true record of the testimony given by  
such witness, to the best of my ability and  
thereafter reduced to typewriting under my  
direction.

I further certify that I am not related to  
any of the parties to this action by blood or  
marriage and that I am in no way interested in  
the outcome of the matter.

In witness whereof, I have hereunto set my  
hand this 19th day of July, 2020.



DEBRA SAPIO LYONS  
CRR, RDR, CRC, CCR, CPE

# **EXHIBIT 11**

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# **EXHIBIT 12**

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# **EXHIBIT 13**

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# **EXHIBIT 14**

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# **EXHIBIT 16**

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# **EXHIBIT 17**

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# EXHIBIT 18



# Low Power, Precision Analog Microcontroller, Dual Sigma-Delta ADCs, Flash/EE, ARM7TDMI

## Data Sheet

## ADuC7060/ADuC7061

### FEATURES

#### Analog input/output

- Dual (24-bit) ADCs
- Single-ended and differential inputs
- Programmable ADC output rate (4 Hz to 8 kHz)
- Programmable digital filters
- Built-in system calibration
- Low power operation mode
  - Primary (24-bit) ADC channel
    - 2 differential pairs or 4 single-ended channels
    - PGA (1 to 512) input stage
    - Selectable input range:  $\pm 2.34$  mV to  $\pm 1.2$  V
    - 30 nV rms noise
  - Auxiliary (24-bit) ADC: 4 differential pairs or 7 single-ended channels
- On-chip precision reference ( $\pm 10$  ppm/ $^{\circ}$ C)
- Programmable sensor excitation current sources
  - 200  $\mu$ A to 2 mA current source range
- Single 14-bit voltage output DAC

#### Microcontroller

- ARM7TDMI core, 16-/32-bit RISC architecture
- JTAG port supports code download and debug
- Multiple clocking options

#### Memory

- 32 kB (16 kB  $\times$  16) Flash/EE memory, including 2 kB kernel
- 4 kB (1 kB  $\times$  32) SRAM

#### Tools

- In-circuit download, JTAG based debug
- Low cost, QuickStart™ development system

#### Communications interfaces

##### SPI interface (5 Mbps)

- 4-byte receive and transmit FIFOs

##### UART serial I/O and I<sup>2</sup>C (master/slave)

#### On-chip peripherals

- 4 $\times$  general-purpose (capture) timers including
  - Wake-up timer
  - Watchdog timer

#### Vectored interrupt controller for FIQ and IRQ

- 8 priority levels for each interrupt type
- Interrupt on edge or level external pin inputs

#### 16-bit, 6-channel PWM

#### General-purpose inputs/outputs

- Up to 14 GPIO pins that are fully 3.3 V compliant

#### Power

- AVDD/DVDD specified for 2.5 V ( $\pm 5\%$ )
- Active mode: 2.74 mA (@ 640 kHz, ADC0 active)
- 10 mA (@ 10.24 MHz, both ADCs active)

#### Packages and temperature range

- Fully specified for  $-40^{\circ}$ C to  $+125^{\circ}$ C operation
- 32-lead LFCSP (5 mm  $\times$  5 mm)
- 48-lead LFCSP and LQFP

#### Derivatives

- 32-lead LFCSP (ADuC7061)
- 48-lead LQFP and 48-lead LFCSP (ADuC7060)

### APPLICATIONS

#### Industrial automation and process control

- Intelligent, precision sensing systems, 4 mA to 20 mA
- loop-based smart sensors

### GENERAL DESCRIPTION

The ADuC7060/ADuC7061 series are fully integrated, 8 kSPS, 24-bit data acquisition systems incorporating high performance multichannel sigma-delta ( $\Sigma$ - $\Delta$ ) analog-to-digital converters (ADCs), 16-bit/ 32-bit ARM7TDMI® MCU, and Flash/EE memory on a single chip.

The ADCs consist of a primary ADC with two differential pairs or four single-ended channels and an auxiliary ADC with up to seven channels. The ADCs operate in single-ended or differential input mode. A single-channel buffered voltage output DAC is available on chip. The DAC output range is programmable to one of four voltage ranges.

The devices operate from an on-chip oscillator and a PLL generating an internal high frequency clock up to 10.24 MHz. The microcontroller core is an ARM7TDMI, 16-bit/32-bit RISC machine offering up to 10 MIPS peak performance; 4 kB of SRAM and 32 kB of nonvolatile Flash/EE memory are provided on chip. The ARM7TDMI core views all memory and registers as a single linear array.

The ADuC7060/ADuC7061 contains four timers. Timer1 is a wake-up timer with the ability to bring the part out of power saving mode. Timer2 is configurable as a watchdog timer. A 16-bit PWM with six output channels is also provided. The ADuC7060/ADuC7061 contains an advanced interrupt controller. The vectored interrupt controller (VIC) allows every interrupt to be assigned a priority level. It also supports nested interrupts to a maximum level of eight per IRQ and FIQ. When IRQ and FIQ interrupt sources are combined, a total of 16 nested interrupt levels is supported. On-chip factory firmware supports in-circuit serial download via the UART serial interface ports and nonintrusive emulation via the JTAG interface. The parts operate from 2.375 V to 2.625 V over an industrial temperature range of  $-40^{\circ}$ C to  $+125^{\circ}$ C.

Rev. F

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**ADuC7060/ADuC7061****Data Sheet****PROCESSOR REFERENCE PERIPHERALS  
INTERRUPT SYSTEM**

There are 15 interrupt sources on the ADuC7060/ADuC7061 that are controlled by the interrupt controller. All interrupts are generated from the on-chip peripherals, except for the software interrupt (SWI), which is programmable by the user. **(The ARM7TDMI CPU core)** recognizes interrupts as one of two types only: a normal interrupt request (IRQ) or a fast interrupt request (FIQ). All the interrupts can be masked separately.

The control and configuration of the interrupt system are managed through a number of interrupt related registers. The bits in each IRQ and FIQ register represent the same interrupt source, as described in Table 65.

Each ADuC7060/ADuC7061 contains a vectored interrupt controller (VIC) that supports nested interrupts up to eight levels. The VIC also allows the programmer to assign priority levels to all interrupt sources. Interrupt nesting needs to be enabled by setting the ENIRQN bit in the IRQCONN register. A number of extra MMRs are used when the full vectored interrupt controller is enabled.

Immediately save IRQSTA/FIQSTA upon entering the interrupt service routine (ISR) to ensure that all valid interrupt sources are serviced.

**Table 65. IRQ/FIQ MMR Bit Designations**

Bit	Description	Comments
0	All interrupts OR'ed (FIQ only)	This bit is set if any FIQ is active
1	Software interrupt	User programmable interrupt source
2	Undefined	This bit is not used
3	Timer0	General-Purpose Timer0
4	Timer1 or wake-up timer	General-Purpose Timer1 or wake-up timer
5	Timer2 or watchdog timer	General-Purpose Timer2 or watchdog timer
6	Timer3 or STI timer	General-Purpose Timer3
7	Undefined	This bit is not used
8	Undefined	This bit is not used
9	Undefined	This bit is not used
10	ADC	ADC interrupt source bit
11	UART	UART interrupt source bit
12	SPI	SPI interrupt source bit
13	XIRQ0 (GPIO IRQ0)	External Interrupt 0
14	XIRQ1 (GPIO IRQ1)	External Interrupt 1
15	I <sup>2</sup> C master IRQ	I <sup>2</sup> C master interrupt source bit
16	I <sup>2</sup> C slave IRQ	I <sup>2</sup> C slave interrupt source bit
17	PWM	PWM trip interrupt source bit
18	XIRQ2 (GPIO IRQ2)	External Interrupt 2
19	XIRQ3 (GPIO IRQ3)	External Interrupt 3

**IRQ**

The IRQ is the exception signal to enter the IRQ mode of the processor. It services general-purpose interrupt handling of internal and external events.

All 32 bits are logically OR'ed to create a single IRQ signal to the ARM7TDMI core. The four 32-bit registers dedicated to IRQ are described in the following sections.

**IRQSIG**

IRQSIG reflects the status of the different IRQ sources. If a peripheral generates an IRQ signal, the corresponding bit in the IRQSIG is set; otherwise, it is cleared. The IRQSIG bits clear when the interrupt in the particular peripheral is cleared. All IRQ sources can be masked in the IRQEN MMR. IRQSIG is read only.

**IRQSIG Register**

Name: IRQSIG  
Address: 0xFFFF0004  
Default value: Undefined  
Access: Read only

**IRQEN**

IRQEN provides the value of the current enable mask. When a bit is set to 1, the corresponding source request is enabled to create an IRQ exception. The IRQEN register cannot be used to disable an interrupt. Clear to 0 has no effect.

**IRQEN Register**

Name: IRQEN  
Address: 0xFFFF0008  
Default value: 0x00000000  
Access: Read and write

**IRQCLR**

IRQCLR is a write-only register that allows the IRQEN register to clear to mask an interrupt source. Each bit that is set to 1 clears the corresponding bit in the IRQEN register without affecting the remaining bits. The pair of registers, IRQEN and IRQCLR, allows independent manipulation of the enable mask without requiring an atomic read-modify-write. Clear to 0 has no effect.

Data Sheet

ADuC7060/ADuC7061

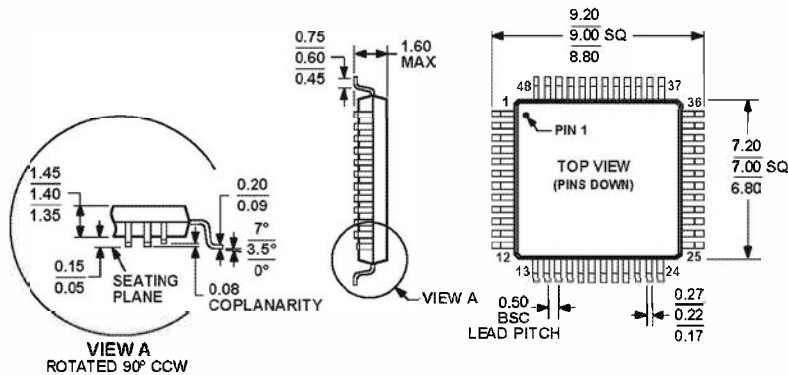


Figure 32. 48-Lead Low Profile Quad Flat Package [LQFP] (ST48)  
Dimensions shown in millimeters

ORDERING GUIDE

Model <sup>1</sup>	Temperature Range	Package Description	Package Option	Ordering Quantity
ADuC7060BCPZ32	−40°C to +125°C	48-Lead Lead Frame Chip Scale Package [LFCSP]	CP-48-5	2,500
ADuC7060BCPZ32-RL	−40°C to +125°C	48-Lead Lead Frame Chip Scale Package [LFCSP]	CP-48-5	
ADuC7060BSTZ32	−40°C to +125°C	48-Lead Low Profile Quad Flat Package [LQFP]	ST-48	2,000
ADuC7060BSTZ32-RL	−40°C to +125°C	48-Lead Low Profile Quad Flat Package [LQFP]	ST-48	
ADuC7061BCPZ32	−40°C to +125°C	32-Lead Lead Frame Chip Scale Package [LFCSP]	CP-32-11	5,000
ADuC7061BCPZ32-RL	−40°C to +125°C	32-Lead Lead Frame Chip Scale Package [LFCSP]	CP-32-11	
EVAL-ADuC7060QSPZ		ADuC7060 Quick Start Plus Development System		
EVAL-ADuC7061MKZ		ADuC7061 Quick Start Evaluation System		

<sup>1</sup> Z = RoHS Compliant Part.

# **EXHIBIT 19**

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# **EXHIBIT 20**

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# EXHIBIT 21





## NGC™ Chromatography Systems

Comprehensive Solutions for Protein Purification

**BIO-RAD**

Chapman Exhibit

7/23/2020

**185**

# DESIGNED BY YOU. BUILT BY BIO-RAD.

## NGC Medium-Pressure Chromatography Systems

The NGC instrument is an automated liquid chromatography system focused on biomolecule purification at the research, process development, and laboratory-scale levels. At the core of the NGC platform is a truly modular and scalable system combined with a single, intuitive software package for system control and evaluation. Together, the NGC Systems provide a total laboratory solution.



### ALIGNS

A single solution that aligns to your needs today and expands to support your future discoveries and throughput requirements



### ADAPTS

A flexible system that adapts to your requirements and can be easily customized to suit your application needs



### ASSURES

An intelligent design that assures functional simplicity and guides you from experimental setup to analysis and support





ALIGNS

A single laboratory chromatography solution that aligns and scales to fit your throughput requirements

NGC Systems can be selected based on customer needs and can be further customized to fit changing customer requirements through the addition of more modules and capabilities.

#### Capabilities included in all NGC Systems

Choice of 10 ml/min or 100 ml/min system pumps, mixer module with multiple mixer barrel options (750 µl, 2 ml, 5 ml, 12 ml), automated sample inject valve, ChromLab™ Software, and a touch screen.

#### Options available for all systems

Compatible with the BioFrac™ Fraction Collector for automated fraction collection (analytical- to preparative-scale) and with the C-96 Autosampler for automated sample application.



#### NGC Quest™ System

Designed for the easy, dependable, and all-purpose purification of biomolecules with accurate gradients and high-resolution separations

##### Base system includes:

- Single-wavelength (UV) and conductivity detection
- ChromLab Software, for fast, easy automated and manual control — single platform compatible with all NGC Systems

#### NGC™ Quest Plus System

Designed for the all-purpose purification of biomolecules and simultaneous detection of proteins, peptides, nucleic acids, and other chromogenic molecules.

##### Includes NGC Quest capability, plus:

- Multi-wavelength (UV/Vis) detection of up to four wavelengths simultaneously



#### NGC Scout™ System

Designed for quick, reliable separations of proteins and peptides. Enables rapid scouting of protein purification conditions with automated gradients and buffer preparation

##### Includes NGC Quest capability, plus:

- Buffer blending valve for automated inline buffer preparation
- pH valve to monitor buffer pH and separation by pH gradients

#### NGC™ Scout Plus System

Designed for the simultaneous detection of proteins, peptides, nucleic acids, and other chromogenic molecules with expanded automation and scouting

##### Includes NGC Scout capability, plus:

- Multi-wavelength (UV/Vis) detection of up to four wavelengths simultaneously



#### NGC Discover™ System

Designed for higher throughput, rapid, and robust method and process development. Provides expanded scouting options with the simultaneous detection of proteins, peptides, nucleic acids, and other chromogenic molecules

##### Includes NGC Scout Plus capability, plus:

- Integrated sample pump, 100 ml/min
- Sample inlet valves
- Column switching valve, 10 ml or 100 ml options

#### NGC™ Discover Pro System

Designed for higher throughput, rapid, and secure method and process development

##### Includes NGC Discover capability, plus:

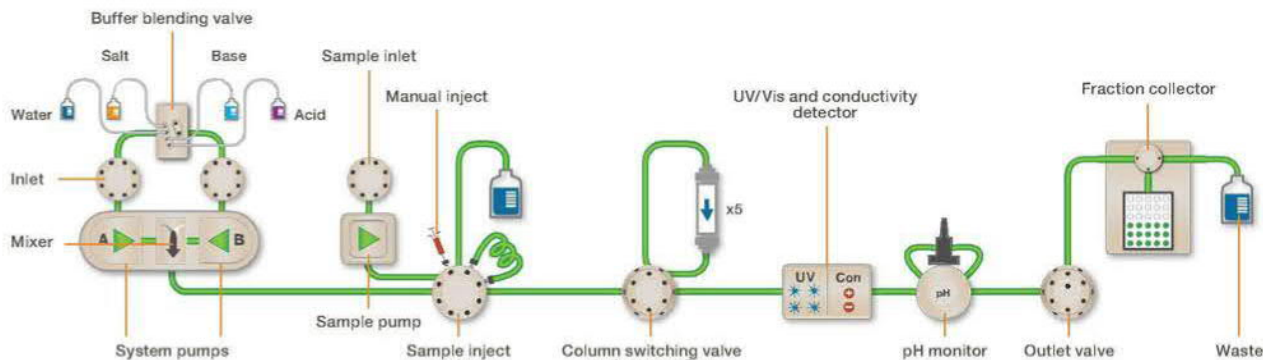
- Sample inlet valve
- Sample outlet valve

##### Options

- Tandem purification with additional column switching valve



# NGC SYSTEM CAPABILITIES



## System Pumps

Pump selection of up to 10 ml/min or 100 ml/min flow rates with the option to switch out pumps to meet your application requirements.

### F10 Pumps

- Flow rate of 0.001–10 ml/min at 3,650 psi (25.2 MPa)
- Ideal for small-scale preparative purifications
- Can also be used for analytical HPLC separations

### F100 Pumps

- Flow rate of 0.01–100 ml/min at 1,450 psi (10 MPa)
- Flexible flow rate range
- Ideal for scale-up applications

## Sample Pump

For automated sample application with the ability to load large sample volumes. Includes an integrated pressure sensor.

## Mixer

Homogenizes buffers from two system pumps and can accommodate varying volumes (different sized barrels are available). Includes a mixer motor and integrated pressure sensor.

## Detectors

Ensure accurate detection of biomolecules such as proteins, peptides, nucleic acids, and chromophores. Include an integrated conductivity monitor (0.01–999 mS/cm) and an optional pH monitor (pH 1–14).

### Single-Wavelength (UV) Detector

For the detection of standard proteins (280 nm) or nucleic acids (255 nm).

### Multi-Wavelength (UV/Vis) Detector

For greater sensitivity and flexible detection of any biomolecules and chromophores (190–800 nm). Simultaneous multi-wavelength (UV/Vis) detection of up to four wavelengths.

## Air Sensor

Detects end of buffer and sample to protect against column damage. Air sensor extension enables use of up to four additional air sensors (eight total).

## Valves

### Sample Inject Valve

For accurate sample loading (µl to L volumes) with a low internal volume for minimal sample loss.

### Buffer Blending Valve

For fast pH scouting with automated inline buffer preparation and the ability to double the fluid output to 20 ml/min or 200 ml/min.

### pH Valve

For accurate, inline pH monitoring (pH 1–14). Includes integrated bypass valve and calibration port for in situ calibration.

### Buffer Inlet Valve

Automated switching between buffers (up to eight inlets per valve) for accelerated method development, column cleaning, and regeneration. Option to include two inlet valves, one for each system pump.

### Column Switching Valve and Reverse Flow

Automated column/media scouting of up to five columns without re-plumbing. Includes reverse flow for rapid elution, sample concentration, and column cleaning. Internal bypass allows automated system priming and cleaning with integrated pressure sensors that measure pre- and delta-column pressures.

### Outlet Valve

For enhanced automated fraction collection of large volume fractions with up to 12 vessels.

## Accessories

### BioFrac Fraction Collector (catalog #741-0002)

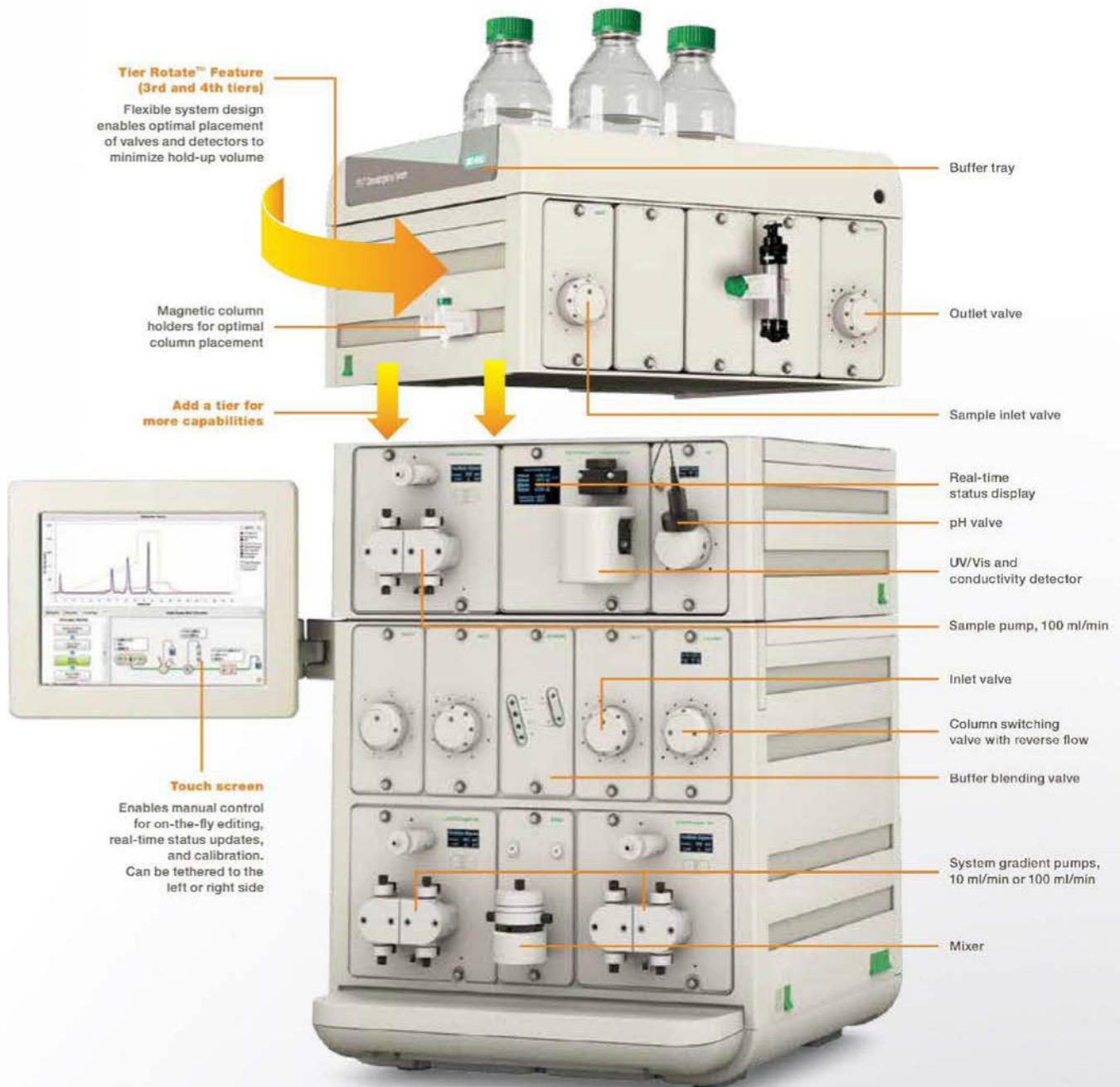
Reliable fraction collection from analytical to preparative scale with versatile capability to collect from 96-well plates to 20 mm tubes — fully compatible with all NGC Systems.

### C-96 Autosampler (catalog #788-5011, #788-5012)

Provides automated, accurate, and reproducible sample injections for optimal sample handling with optional cooling. Includes SIM I/O module and cable for seamless integration with the NGC Systems (#788-4016 and #788-5013, respectively).



## PERSONALIZE AND EXPAND YOUR SYSTEM CAPABILITIES TO SUIT YOUR APPLICATION NEEDS AND WORKFLOW

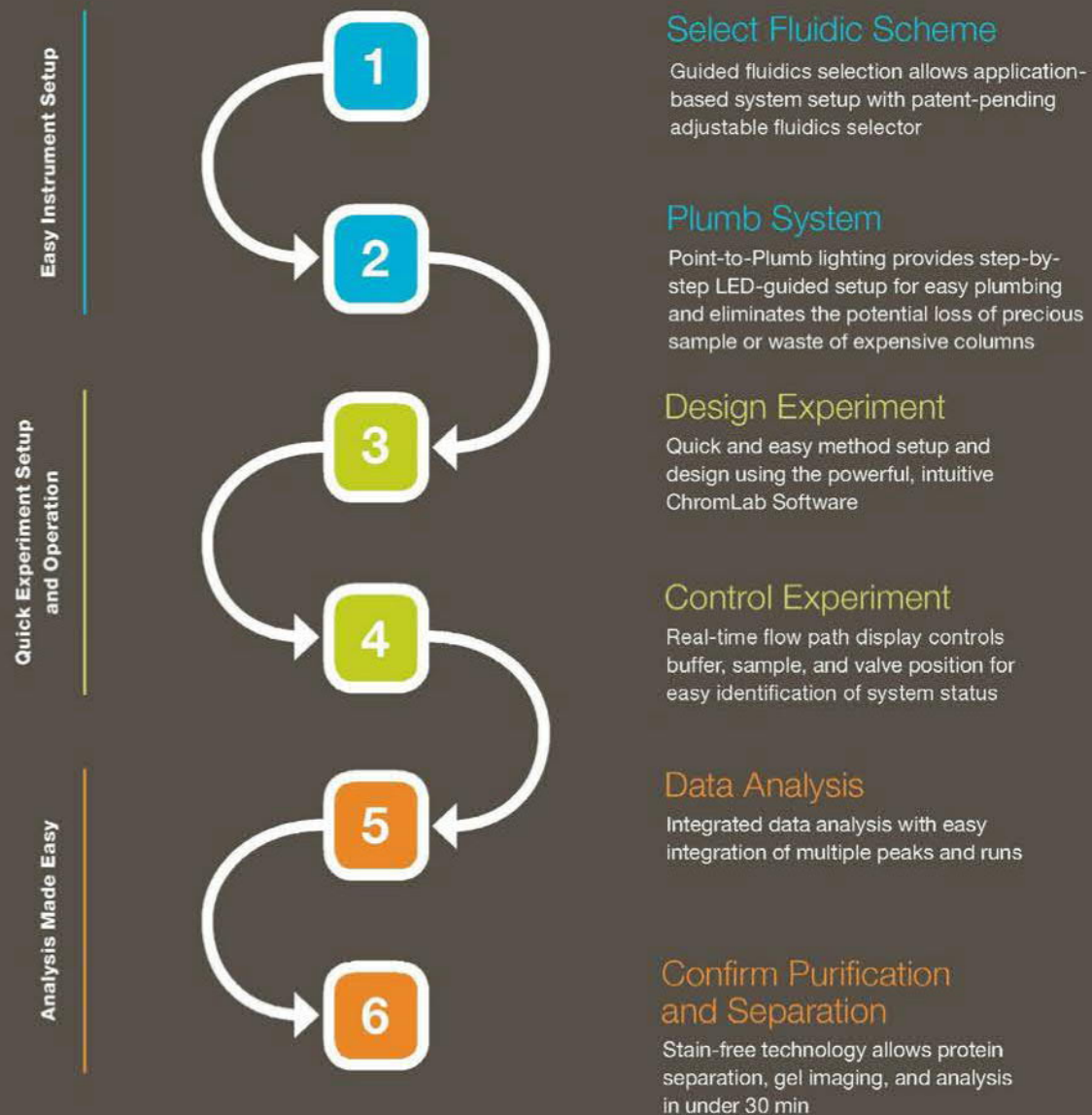






ADAPTS

Powerful ChromLab Software control, transferable across all NGC Systems, enables minimal training and fast setup to analysis.



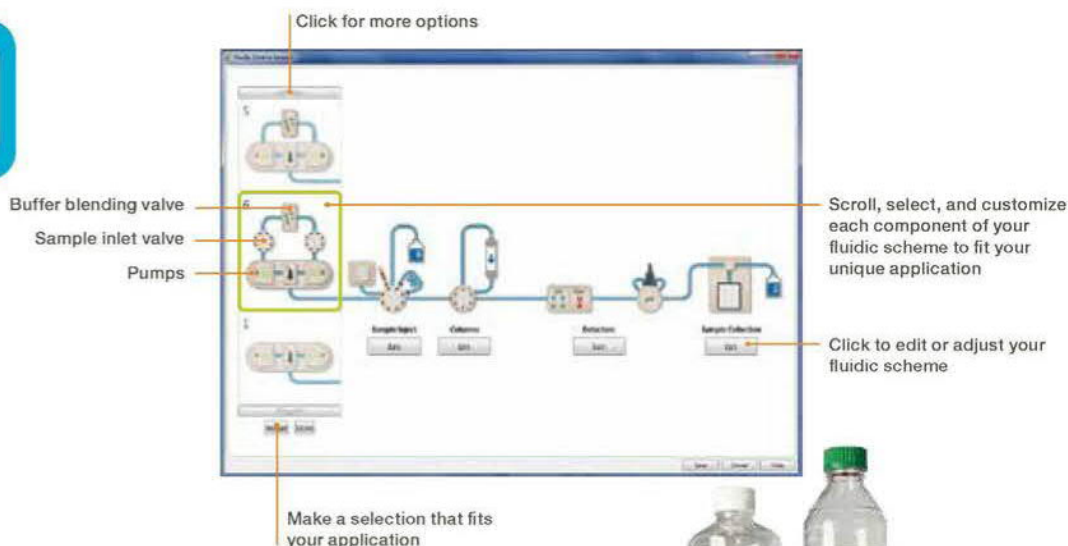
## EASY INSTRUMENT SETUP

1

### Select Fluidic Scheme

Select the fluidic scheme that best fits your application, set a default path, and optimize your module placement

To view the complete module library see bulletin 6326 or the NGC System Tour at [bio-rad.com/NGCsystems](http://bio-rad.com/NGCsystems)



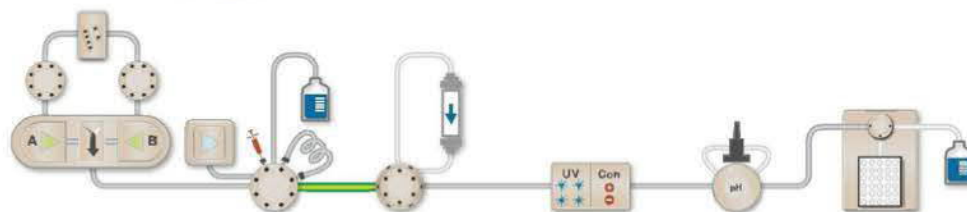
**Choose** new modules to add to your system capabilities (for example, add a sample pump for loading large sample volumes)

**Change** module locations to adjust to your application and achieve optimal results

2

### Plumb System

Point-to-Plumb™ intuitive graphical indicators for simple, guided LED plumbing setup



Click on each step in the flow path to guide system plumbing. Then, appropriate LEDs will light up to guide plumbing (as shown above).

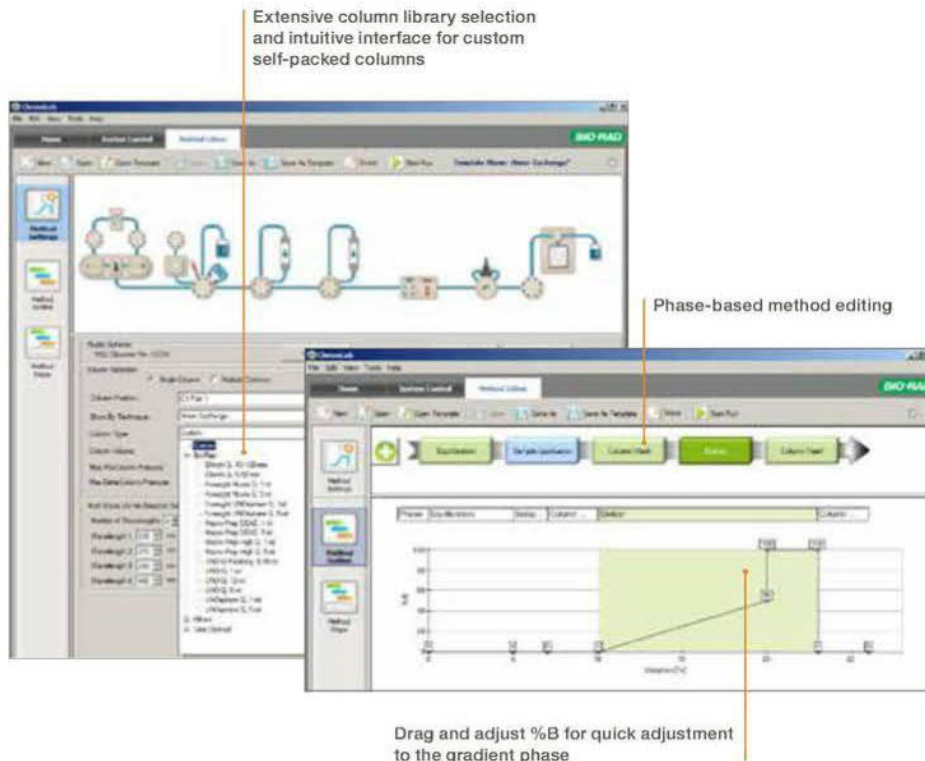


## QUICK EXPERIMENT SETUP AND OPERATION

3

### Design Experiment

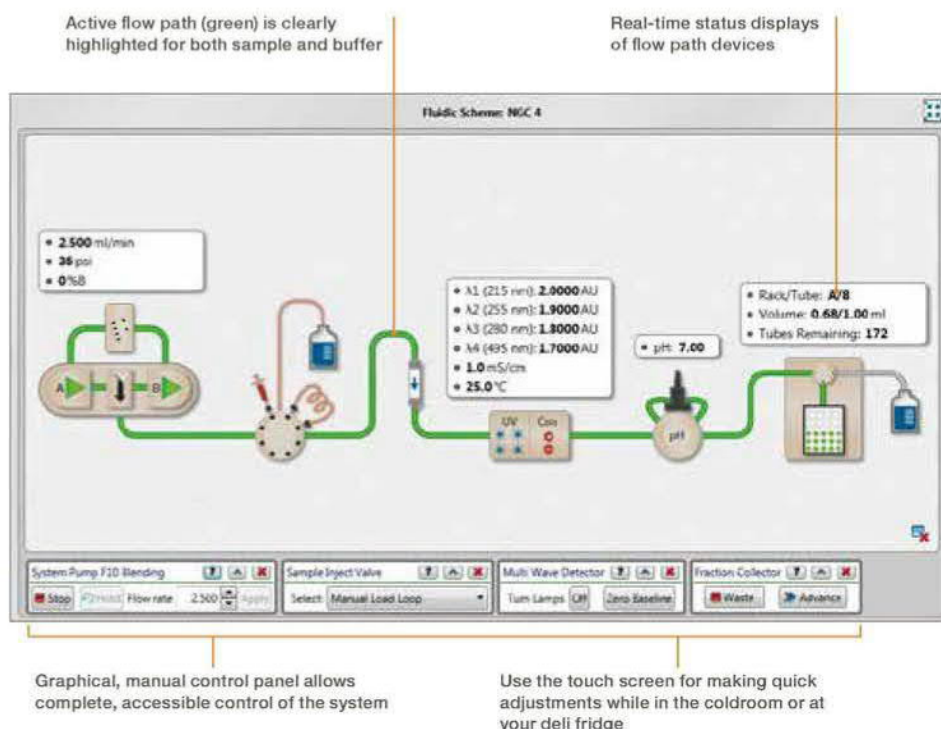
The ChromLab Method Editor enables confident, automated walk-away purification



4

### Control Experiment

Manual controls conveniently located for quick and easy access provide total graphical user control of the NGC System with a coldroom-compatible touch screen or a computer



For further details see the NGC System Tour at [bio-rad.com/NGCsystems](http://bio-rad.com/NGCsystems)



## ANALYSIS MADE EASY

5

### Data Analysis

Comprehensive data analysis that enables fast, accurate data comparison

Ability to overlay and zoom in on multiple chromatograms

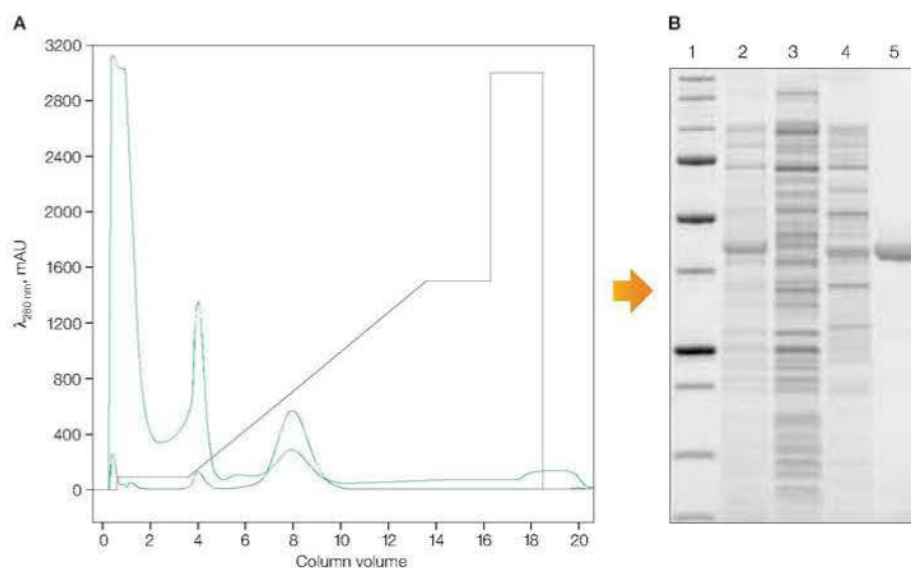


Simple peak integration across multiple runs with single button auto-integration

6

### Confirm Purification and Separation

Stain-free technology allows protein separation, gel imaging, and analysis in under 30 min



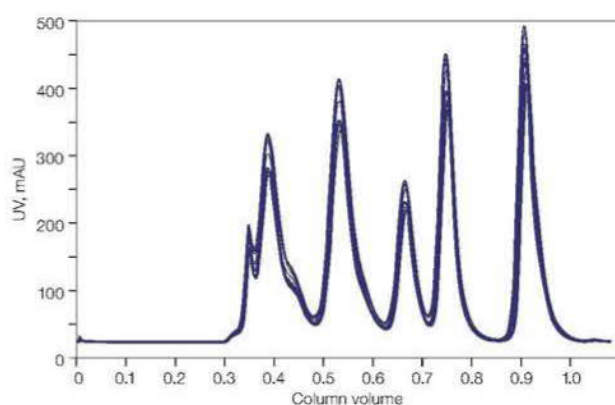
**Visual confirmation of chromatography results using stain-free gels and imaging.** **A**, Isolation of a histidine-tagged GFP protein from a crude *E. coli* lysate by affinity chromatography using an IMAC column. **B**, Purification was confirmed by SDS-PAGE using a Criterion™ TGX Stain-Free™ Gel run for 20 minutes and directly visualized on the Gel Doc™ EZ Imaging System without the need for Coomassie staining. Samples in lanes 2 (crude *E. coli* lysates), 3 (flowthrough from the IMAC column), 4 (10% imidazole column wash), and 5 (purified histidine-tagged GFP protein) were compared against Precision Plus Protein™ Unstained Standards (lane 1).



Intelligent design that guides your setup and operation

## Pre-plumbed system

QC-validated performance optimized for low hold-up volume translates to more reproducible results and sharper peaks



**High-quality results with reproducible separations.** Eleven overlaid separations of a Bio-Rad size exclusion standard — composed of thyroglobulin,  $\gamma$ -globulin, ovalbumin, myoglobin, and vitamin B12 — performed on the NGC Quest System with a 10 x 300 mm size exclusion column.

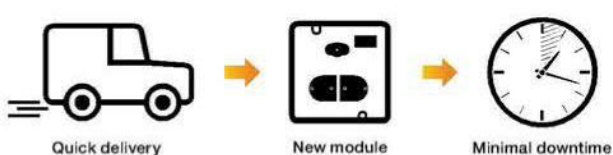
## Real-time status displays

Provide immediate status of important parameters for clear diagnostics of key NGC instrument modules



## Module replacement service

Directly replace plug and play modules — eliminate lengthy downtime and costly service visits

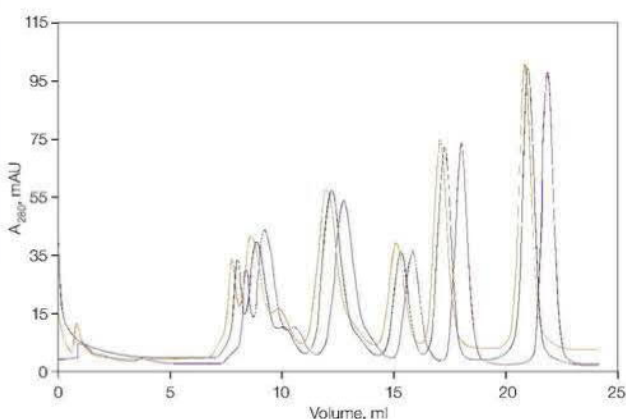


## Open platform

Compatible with all medium-pressure columns and ChromLab Software includes method templates with column libraries



Validated column applications on the NGC System



**Completely transferable applications.** Identical comparisons of a Bio-Rad size exclusion standard (catalog #151-1901) performed on a Superdex 200 10/300 GL Size Exclusion Column with separations performed on the NGC Quest (—), ÄKTApurifier (—), and ÄKTA avant (—) Systems.

## SELECTION GUIDE

		NGC Chromatography Systems											
		NGC Quest 10 788-0001	NGC Quest 10 Plus 788-0003	NGC Quest 100 788-0002	NGC Quest 100 Plus 788-0004	NGC Scout 10 788-0005	NGC Scout 10 Plus 788-0007	NGC Scout 100 788-0006	NGC Scout 100 Plus 788-0008	NGC Discover 10 788-0009	NGC Discover 100 788-0010	NGC Discover 10 Pro 788-0011	NGC Discover 100 Pro 788-0012
Catalog #	Product description												
788-4002	NGC F10 Pump Module	•	•			•	•		•	•	•	•	
788-4003	NGC F100 Pump Module			•	•			•	•		•		•
788-4018	NGC Mixer Module	•	•	•	•	•	•	•	•	•	•	•	•
788-4007	NGC Sample Inject Valve Module	•	•	•	•	•	•	•	•	•	•	•	•
788-4008	NGC Single-Wavelength Detector Module, includes conductivity monitor	•		•		•		•					
788-4009	NGC Multi-Wavelength Detector Module, includes conductivity monitor	○	•	○	•	○	•	○	•	•	•	•	•
788-4010	NGC Buffer Blending Valve Module	○	○	○	○	•	•	•	•	•	•	•	•
788-4011	NGC pH Valve Module, includes pH probe	○	○	○	○	•	•	•	•	•	•	•	•
788-4004	NGC Sample Pump Module, integrated	○	○	○	○	○	○	○	•	•	•	•	•
788-4006	NGC Inlet Valve Module	○	○	○	○	○	○	○	•	•	•	•	•
788-4012	NGC Column Switching Valve Module, 10 ml	○	○	○	○	○	○	○	•	○	•	•	○
788-4026	NGC Column Switching Valve Module, 100 ml	○	○	○	○	○	○	○	○	•	○	•	•
788-4013	NGC Outlet Valve Module	○	○	○	○	○	○	○	○	○	•	•	•
788-6000	ChromLab Software	•	•	•	•	•	•	•	•	•	•	•	•

- Standard
- Optional

**Note:** All NGC Systems include a touch screen and NGC Fittings Kit (catalog #788-4017) and are compatible with the BioFrac Fraction Collector and C-96 Autosampler.





**Specifications****System Specifications**

<b>Control system</b>	ChromLab Software (compatible across all NGC Systems)
<b>Dimensions (D x W x H)</b>	61 x 49 x 56 cm (NGC Quest and NGC Scout Systems)  61 x 49 x 74 cm (NGC Discover System)
<b>Weight (excluding computer)</b>	41–46 kg (NGC Quest and NGC Scout Systems)  64 kg (NGC Discover System)
<b>Power supply</b>	100–240 V, 50–60 Hz
<b>Power consumption</b>	750 W maximum

**System Pump**

<b>Pump type</b>	Reciprocating piston
<b>Flow rate setting</b>	<b>10 ml/min pumps:</b> 0.001 to 10 ml/min (normal range)  <b>100 ml/min pumps:</b> 0.01 to 100 ml/min (normal range)
<b>Flow rate accuracy</b>	±2% (conditions: F10 pump — 0.1 to 10 ml/min, F100 pump — 1.0 to 100 ml/min; pressure: <600 psi (4.1 MPa, 41 bar); viscosity: 0.5–3.7 cP)
<b>Pressure range</b>	<b>10 ml/min pumps:</b> 0 to 25.2 MPa (3,650 psi)  <b>100 ml/min pumps:</b> 0 to 10 MPa (1,450 psi)
<b>Viscosity range</b>	0.5–10.8 cP (for 10 ml/min and 100 ml/min pumps)

**Sample Pump**

<b>Pump type</b>	Piston pump, metering type
<b>Flow rate setting</b>	0.01 to 100 ml/min
<b>Flow rate accuracy</b>	±2%
<b>Pressure range</b>	0 to 10 MPa (1,450 psi)
<b>Viscosity range</b>	0.5–10 cP

**Mixer**

<b>Mixing principle</b>	Chamber with magnetic stirrer
<b>Mixer volume</b>	263 µl (included), 750 µl (included), 2 ml, 5 ml (F10)  750 µl (included), 2 ml (included), 5 ml, 12 ml (F100)
<b>Gradient composition accuracy</b>	± 0.5% (conditions: 3 to 97%B, 0.25 to 10 ml/min F10 pumps)  ± 0.8% (conditions: 5 to 95%B, 1 to 100 ml/min F100 pumps)

**Valves**

<b>Type</b>	Rotary valves and rocker solenoid
<b>Number of valves</b>	Up to 12
<b>Functions</b>	Loop selection (PEEK Loop and DynaLoop™ offerings)

**Pressure Sensors**

<b>Placement of sensors</b>	Standard: after system pump  Options: pre-column, post-column
<b>Range</b>	0–3,650 psi
<b>Accuracy</b>	± 2 psi or 2%, whichever is greater

**Inlet Valves**

<b>Inlet A</b>	8 inlets
<b>Inlet B</b>	8 inlets
<b>Sample inlet</b>	8 inlets

**UV and UV/Vis Detectors**

(each includes an integrated conductivity monitor)

<b>Wavelength</b>	<b>Single-wavelength:</b> 255 nm (nucleic acids) or 280 nm (proteins) <b>Multi-wavelength (up to 4):</b> 190–800 nm
<b>Absorbance range</b>	0 to >2.8 AU
<b>Linearity</b>	0 to 2 AU within ±5%
<b>Operating pressure</b>	1,450 psi (10 MPa) for 5, 10 mm flow cells 700 psi (5 MPa) for 2 mm flow cells
<b>Flow cells</b>	Preparative: 2 mm (cell volume: 20 µl) Analytical: 5 mm (cell volume: 9 µl) Analytical: 10 mm (cell volume: 18 µl)

**Conductivity Monitor**

<b>Conductivity reading range</b>	0.01–999 mS/cm
<b>Accuracy</b>	±2%
<b>Operating pressure</b>	0–5.5 MPa (800 psi)
<b>Flow cell volume</b>	6 µl
<b>Temperature monitor range</b>	4–100°C
<b>Temperature monitor accuracy</b>	±2%

**pH Monitor**

<b>pH reading range</b>	0 to 14
<b>Accuracy</b>	±0.1 pH unit within pH 2–12
<b>Operating pressure</b>	0 to 70 psi with pH probe inline and 0–500 psi in bypass mode
<b>Flow cell volume</b>	100 µl (210 µl including internal flow paths)

**BioFrac Fraction Collector**

<b>Collection modes</b>	Time: 0.02–99,999 min Drop: 1–99,999 drops, flow rate ≤5.0 ml/min Volume: 0.02–99,999 ml
<b>Collection rack options</b>	180 x 12–13 mm tubes, 120 x 15–16 mm tubes, 80 x 18–20 mm tubes, 168 x 1.5 ml microtubes, 24 x 30 mm tubes, 4 x 96, 48-, 24-, or 12-position microplates, and 20 x unlimited preparative volumes adaptor
<b>Operating temperature</b>	4–40°C
<b>Dimensions (W x D x H)</b>	44.5 x 35.6 x 38.7 cm
<b>Safety</b>	Meets IEC 61010 and CSA 22.2 certification

**Column Switching**

<b>Five-column valve</b>	Can connect up to five columns with forward and reverse flow and bypass capability
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**Buffer Blending**

	Standard in the NGC Scout and NGC Discover Systems
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**Air Sensor Module**

<b>Number of sensors</b>	Up to 8 total air sensors (1 for end of sample detection, remaining are buffer)
<b>Placement of built-in sensors</b>	End of buffer, end of sample
<b>Sensing principle</b>	Acoustic

**Note:** All NGC Systems include a touch screen and are compatible with the BioFrac Fraction Collector and C-96 Autosampler.

## Ordering Information

### NGC Medium-Pressure Chromatography Systems

#### NGC Quest Chromatography Systems

For the all-purpose purification of biomolecules

788-0001	NGC Quest 10 System
788-0003	NGC Quest 10 Plus System
788-0002	NGC Quest 100 System
788-0004	NGC Quest 100 Plus System

#### NGC Scout Chromatography Systems

For rapid scouting of biomolecules

788-0005	NGC Scout 10 System
788-0006	NGC Scout 100 System

For rapid scouting of proteins, peptides, and nucleic acids

788-0007	NGC Scout 10 Plus System
788-0008	NGC Scout 100 Plus System

#### NGC Discover Chromatography Systems

For method development

788-0009	NGC Discover 10 System
788-0010	NGC Discover 100 System

### NGC System Modules and Accessories

#### System Pumps

788-4002	NGC F10 Pump Module, pkg of 1, includes 10 ml/min system pump kit with necessary tubing and fittings, for creating buffer gradients, for use with the buffer blending valve to generate flow rates of up to 20 ml/min
788-4003	NGC F100 Pump Module, pkg of 1, includes 100 ml/min system pump kit with necessary tubing and fittings, for creating buffer gradients, for use with the buffer blending valve to generate flow rates of up to 200 ml/min

#### Sample Pump

788-4004	NGC Sample Pump 100 Module, pkg of 1, includes 100 ml/min sample pump kit with necessary tubing and fittings, for automated large-volume sample application via sample inject valve
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#### Detectors

788-4008	NGC Single-Wavelength Detector Module, pkg of 1, includes UV/conductivity detector with necessary tubing and fittings, for nucleotide and protein detection, salt gradient generation
788-4009	NGC Multi-Wavelength Detector Module, pkg of 1, includes UV/Vis and conductivity detector kit with necessary tubing and fittings, for simultaneous four-wavelength monitoring of elution fractions between 190–800 nm and salt gradient generation

#### Mixer

788-4018	NGC Mixer Module, pkg of 1, can be extended with 2, 5, and 12 ml barrels for efficient gradient mixing at higher flow rates, for use with all NGC Systems, does not include mixer base or barrels
788-4019	NGC F100 Mixer, pkg of 1, 750 µl base and top assembly, included with all 100 ml/min NGC Systems
788-4020	NGC F10 Mixer, pkg of 1, 263 µl base and top assembly, included with all 10 ml/min NGC Systems
788-4021	NGC F10 Mixer Barrel Kit, pkg of 1, 750 µl extension barrel for F10 263 µl mixer, part of NGC Scout 10, NGC Discover 10 Systems
788-4022	NGC F10 Mixer Barrel Kit, pkg of 1, 2 ml extension barrel for F10 263 µl mixer, optional part
788-4028	NGC F100 Mixer Barrel Kit, pkg of 1, 2 ml extension barrel for F100 750 µl mixer, part of NGC Scout 100, NGC Discover 100 Systems
788-4023	NGC F100 Mixer Barrel Kit, pkg of 1, 5 ml extension barrel for F100 750 µl mixer, optional part
788-4024	NGC F100 Mixer Barrel Kit, pkg of 1, 12 ml extension barrel for 750 µl mixer, optional part

#### Valves

788-4010	NGC Buffer Blending Valve Module, pkg of 1, kit includes necessary tubing and fittings, for inline buffer preparation and generating pH gradients for quick pH scouting
788-4006	NGC Inlet Valve Module, pkg of 1, kit includes necessary tubing and fittings, for automated switching between multiple buffers and samples during method development
788-4011	NGC pH Valve Module, pkg of 1, kit includes the pH valve kit, pH probe, tubing, and fittings for accurate inline pH measurement
788-4012	NGC Column Switching Valve Module (10 ml), kit includes the necessary tubing and fittings to accommodate the most common column types, holds 5 columns, for use with F10 systems and multiple columns for quick column scouting and reverse flow
788-4026	NGC Column Switching Valve Module (100 ml), kit includes the necessary tubing and fittings to accommodate the most common column types, holds 5 columns, for use with F100 systems and multiple columns for quick column scouting and reverse flow
788-4013	NGC Outlet Valve Module, pkg of 1, kit includes necessary tubing and fittings for automated fraction collection of large-volume fractions with up to 12 vessels

#### Air Sensor

788-5017	NGC Air Sensor Module, pkg of 1, kit includes 2 large-bore air sensors to protect against air entering pumps and columns, supports up to 4 large- and small-bore air sensors, for detection of end of buffer and sample
788-5018	NGC Air Sensor Extension Module, pkg of 1, connects to the base air sensor module to support 4 additional air sensors, does not include any air sensors, optional part
788-5020	NGC Air Sensor (small), pkg of 1, includes air sensor to exclude air from system and columns, detects air in small-diameter PEEK Tubing
788-5021	NGC Air Sensor (large), pkg of 1, includes air sensor to exclude air from system and columns, detects air in large-diameter tubing
788-5019	NGC Air Sensor Extension Cable, pkg of 1, for placement of air sensors outside air sensor module

#### Fraction Collector and Autosampler

741-0002	BioFrac Fraction Collector, 100/240 V, fraction collector compatible with all NGC Systems, includes power cord, rack set F1 (2 x flatpack, 13 mm), BioFrac Diverter Valve, fittings kit
788-4025	NGC Communication Adaptor, pkg of 1, enables communication with Bio-Rad devices, such as the BioFrac Fraction Collector (#741-0002), with the NGC System
788-5011	C-96 Autosampler, 110/240 V, includes standard 84+3 vial tray (1.5 and 10 ml), control cable set to connect with NGC System, 1 ml syringe, 2 ml sample loop, also includes #760-5014, #760-5026, #760-0604, #788-4016, and #788-5013, compatible with all NGC Systems
788-5012	C-96 Autosampler with cooling, 110/240 V, with Peltier cooling, includes standard 84+3 vial tray (1.5 and 10 ml), control cable set to connect with NGC System, 1 ml syringe, 2 ml sample loop, also includes #760-5014, #760-5026, #760-0604, #788-4016, and #788-5013, compatible with all NGC Systems

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# DESIGNED BY YOU BUILT BY BIO-RAD

**BIO-RAD**



Available on the  
**App Store**



Download the NGC System Tour on the App Store  
and use this Augmented Reality (AR) Target to visualize  
the NGC System in your lab.



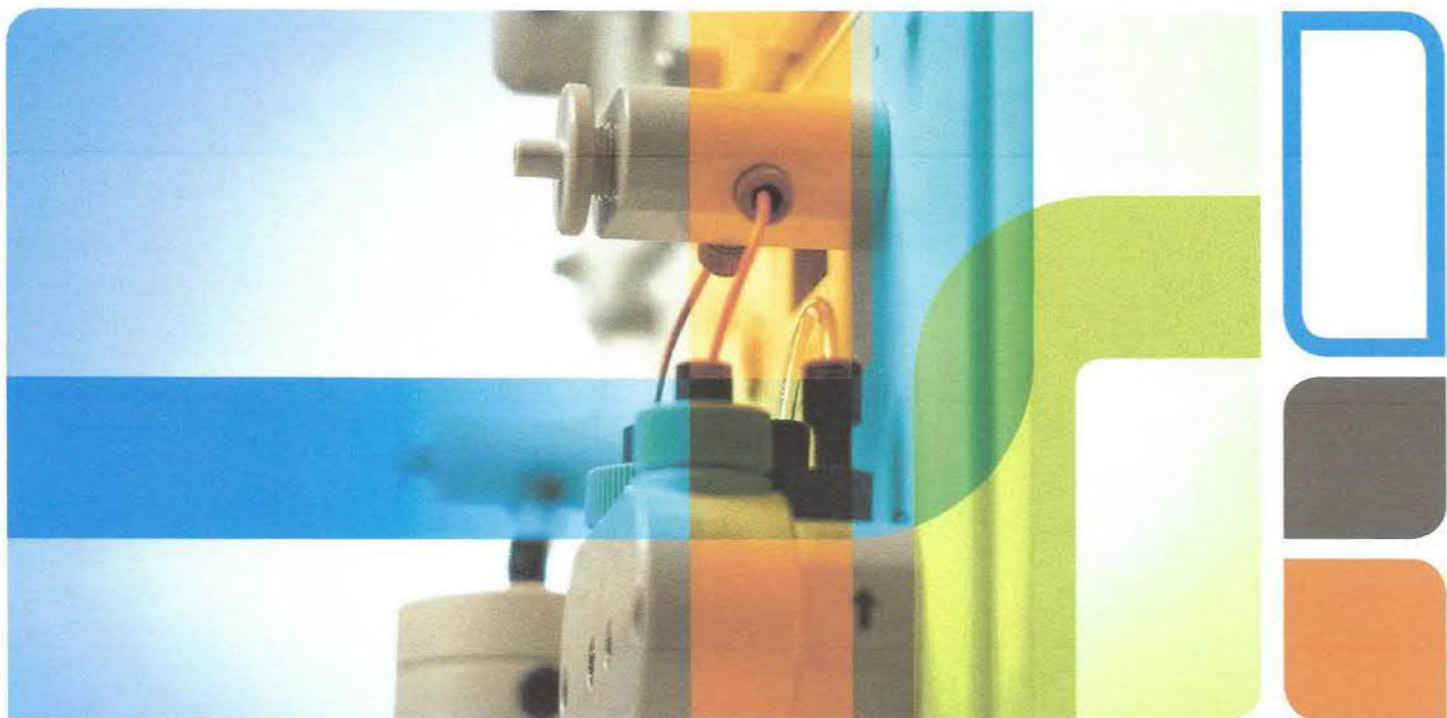
**BIO-RAD**

**Bio-Rad  
Laboratories, Inc.**

Life Science  
Group

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**Canada** 905 364 3435 **China** 86 21 6169 8500 **Czech Republic** 420 241 430 532 **Denmark** 44 52 10 00 **Finland** 09 804 22 00  
**France** 01 47 95 69 65 **Germany** 49 89 31 884 0 **Greece** 30 210 9532 220 **Hong Kong** 852 2789 3300 **Hungary** 36 1 459 6100 **India** 91 124 4029300  
**Israel** 03 963 6050 **Italy** 39 02 216091 **Japan** 81 3 6361 7000 **Korea** 82 2 3473 4460 **Mexico** 52 555 488 7670 **The Netherlands** 0318 540666  
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# EXHIBIT 22



NGC™ Chromatography Systems  
**Multidimensional (Multi-D) Plumbing Guide**  
Version 1.0

**BIO-RAD**

Chapman Exhibit

7/24/2020

**215**



## Introduction

This guide is designed to help plumb your NGC System for multidimensional (Multi-D) chromatography applications. These techniques can help enhance sample recovery and improve productivity by minimizing the steps and time required for protein purification. In addition, it shows the optimal locations for module placement to minimize tubing length and swept volume.

Traditionally, multistep purifications have been labor intensive and time consuming, as fractions from a run are collected, pooled, and often dialyzed before being injected onto the next column. With the NGC System, well-characterized single-step purifications are combined to create tandem or automated multicolumn protocols, significantly decreasing sample loss and the time spent on the protein purification process. Typically, the columns in the combined methods have different chemistries or binding characteristics, enhancing selectivity, peak separation, and resolution.

In tandem chromatography, proteins of interest can be eluted from the first column and loaded directly onto a second column plumbed in series followed by analysis using the UV detector. For a tandem chromatography run to be successful, certain considerations must be taken into account, including the binding capacity of both columns, the optimal buffer composition (including pH and salt concentration), and the pressure ratings for both columns.

In two-step automated multicolumn (2-D) chromatography, proteins of interest are eluted from the first column (often an affinity column) and held in a sample loop before being injected directly onto a second column. With this technique, column pressure ratings and buffer conditions are not critical factors for a successful separation.

Using this plumbing guide in conjunction with the numerous tandem and 2-D templates in ChromLab™ Software should help you successfully set up and run your methods and achieve your protein purification goals more quickly and efficiently. Refer to the Multidimensional Chromatography Success Guide (bulletin 6701) for more information about Multi-D.

## 2-TIER + 2 CSV for tandem chromatography applications

Simple system configuration for tandem affinity and desalting columns. Proteins are eluted from the affinity column directly onto the desalting column.

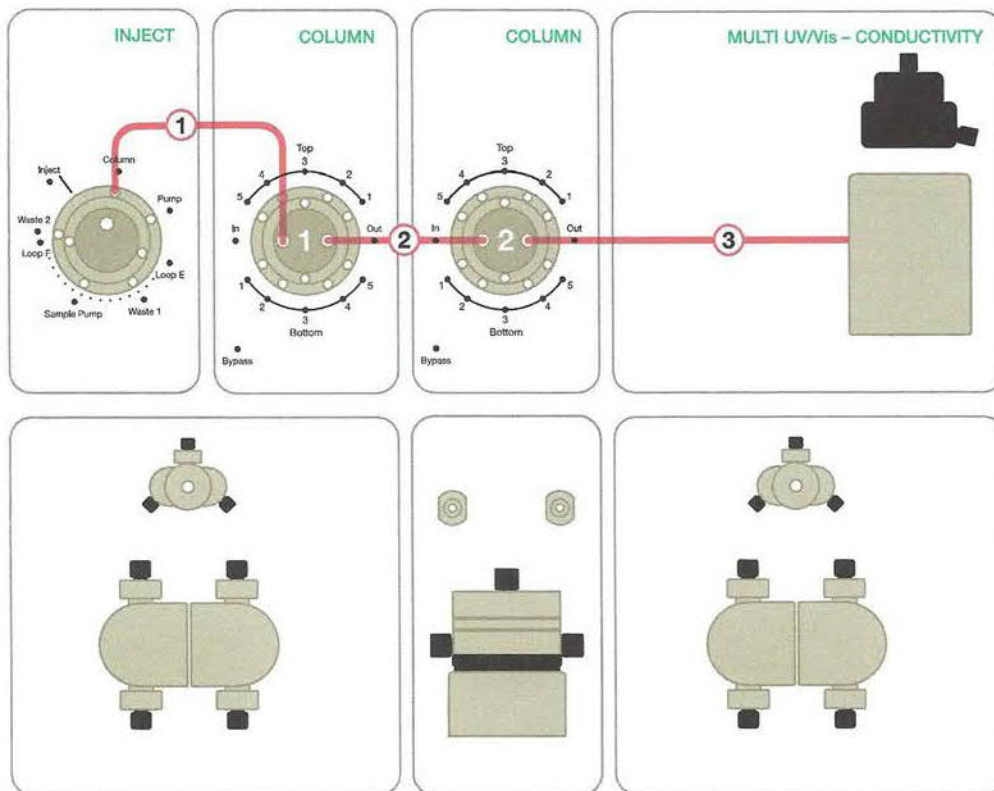
### Example Templates

Affinity 1 ml – Desalting

Affinity 5 ml – Desalting

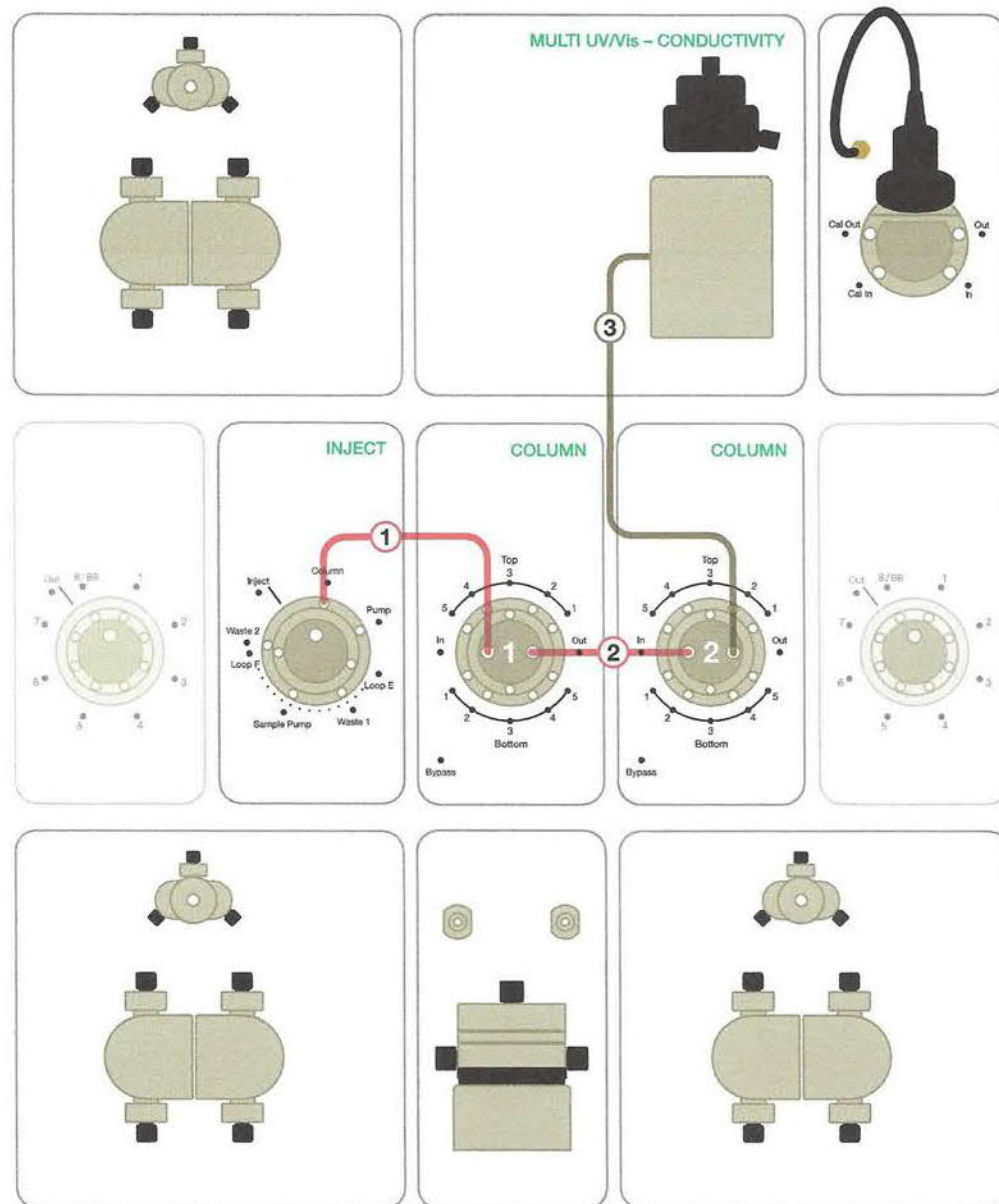
### Tubing

- 1** Tube #2 – Length: 17 cm  
Inject Valve Column to Column  
Switching Valve 1 In
- 2** Tube #2 – Length: 17 cm  
Column Switching Valve 1 Out  
to Column Switching Valve 2 In
- 3** MWD:  
Tube #2 – Length: 17 cm  
Column Switching Valve 2 Out  
to Multi-Wavelength Detector In  
**OR**  
SWD (not shown):  
Tube #1 – Length: 24.5 cm  
Column Switching Valve 2 Out  
to Single-Wavelength Detector In



## 3-TIER + 2 CSV for tandem chromatography applications

3-tier system for tandem affinity and desalting columns. Proteins are eluted from the affinity column directly onto the desalting column.



### Example Templates

- Affinity 1 ml — Desalting
- Affinity 5 ml — Desalting
- Affinity 1 ml — Linear Gradient
- Affinity 1 ml — Step Gradient
- Affinity 5 ml — Linear Gradient
- Affinity 5 ml — Step Gradient

### Tubing

- 1** Tube #2 — Length: 17 cm  
Inject Valve Column to  
Column Switching Valve 1 In
- 2** Tube #2 — Length: 17 cm  
Column Switching Valve 1 Out  
to Column Switching Valve 2 In
- 3** MWD:  
Tube #10 — Length: 33.5 cm  
Column Switching Valve 2 Out  
to Multi-Wavelength Detector In  
OR  
SWD (not shown):  
Tube #1 — Length: 24.5 cm  
Column Switching Valve 2 Out  
to Single-Wavelength Detector In

Additional modules (grayed out) are shown in the optimal positions to minimize tubing length and swept volume.



**Bio-Rad  
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*Web site bio-rad.com USA 1 800 424 6723 Australia 61 2 9914 2800 Austria 43 1 877 89 01 177 Belgium 32 (0)3 710 53 00 Brazil 55 11 3065 7550  
Canada 1 905 364 3435 China 86 21 6169 8500 Czech Republic 420 241 430 532 Denmark 45 44 52 10 00 Finland 358 09 804 22 00  
France 33 01 47 95 69 65 Germany 49 89 31 884 0 Hong Kong 852 2789 3300 Hungary 36 1 459 6100 India 91 124 4029300  
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Singapore 65 6415 3188 South Africa 27 (0) 861 246 723 Spain 34 91 590 5200 Sweden 46 08 555 12700 Switzerland 41 026 674 55 05  
Taiwan 886 2 2578 7189 Thailand 66 662 651 8311 United Arab Emirates 971 4 8187300 United Kingdom 44 020 8328 2000*



# **EXHIBIT 23**

**FILED UNDER SEAL**









# **EXHIBIT 24**

**FILED UNDER SEAL**







# **EXHIBIT 25**

**FILED UNDER SEAL**





















# **EXHIBIT 26**

**FILED UNDER SEAL**























# **EXHIBIT 27**

**FILED UNDER SEAL**



















# **EXHIBIT 28**

**FILED UNDER SEAL**







# **EXHIBIT 29**

**FILED UNDER SEAL**









# **EXHIBIT 30**

**FILED UNDER SEAL**







# EXHIBIT 31



**NGC Chromatography Systems  
and ChromLab Software**  
**Installation Guide**  
Version 6.0



Chapman Exhibit  
7/24/2020  
**212**

# **NGC Chromatography Systems and ChromLab Software Installation Guide**

**Version 6.0**





## **Bio-Rad Technical Support Department**

The Bio-Rad Technical Support department in the U.S. is open Monday through Friday, 5:00 AM to 5:00 PM.

**Phone:** 1-800-424-6723, option 2

**Email:** [Support@bio-rad.com](mailto:Support@bio-rad.com) (U.S./Canada only)

For technical assistance outside the U.S. and Canada, contact your local technical support office or click the Contact us link at [www.biorad.com](http://www.biorad.com).

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# 1 Introduction

The NGC chromatography systems are preparative systems designed to rapidly automate the purification of biomolecules. The flexible, modular, and economical design makes NGC the instrument of choice for method development and scale-up. It is available in six preplumbed, factory-tested configurations at two different flow rates. Each preconfigured system can be further customized and upgraded by adding valves, detectors, or pumps in order to meet specific application needs. Any system can be configured for either low flow rate or high flow rate operation by simply changing the system pump modules. As a result, a single hardware platform can be modified as the application need and scale change.

ChromLab software enables you to control, manage, and evaluate the NGC system and the purification runs.

## Main Features

NGC chromatography systems enable you to do the following:




- Easily create purification and maintenance protocols from predefined method templates and protocol phases
- Automate multicolumn purification processes using preprogrammed templates and multiple column switching valves
- Automate multiple sample injections using either the sample inlet valve and the sample pump or the C-96 autosampler
- Expand sample monitoring using the signal import module (SIM) to export digital signals to, and import digital signals from, external detectors
- Collect large-volume fractions using multiple outlet valves while also collecting small-volume fractions using the BioFrac fraction collector
- Automatically prepare buffers using preprogrammed buffer blending protocols
- Analyze purification results through 1-click peak integration, determine protein concentration, and calculate column performance
- Automate purification protocol optimization using the scouting wizard
- Easily locate fractions containing peaks of interest and view the protein concentration within each fraction
- Extend the preconfigured systems with additional valves for buffers, samples, and columns
- Organize the location of the modules to optimize separation performance based on method scale and complexity, and to minimize the system swept volume
- Minimize errors when connecting tubing using the Point-to-Plumb feature in ChromLab software

Safety Information

This section explains the different safety alerts within this document. This section also provides information about the safe use and setup of the instrument.

Safety Alerts

This document contains **WARNINGS** and **Cautions** pertaining to the installation and use of the NGC instrument.

Alert Icon		Definition
	Flammable/ Extreme Heat	A hazardous situation that could result in serious personal injury or extreme damage to the instrument. Do not proceed until all stated conditions are met and clearly understood.
	Electrical Shock	A hazardous situation that could result in serious personal injury or extreme damage to the instrument. Do not proceed until all stated conditions are met and clearly understood.
		A hazardous situation that could result in minor or moderate personal injury or damage to the instrument. Do not proceed until all stated conditions are met and clearly understood.

Safety Precautions



**Caution:** The weight of the NGC system varies from moderate to heavy depending on the system in place. Take care when lifting the instrument onto the lab bench or into a standard cold cabinet. To reduce the risk of personal injury or damage to the instrument, three or more people should perform this task.



**WARNING!** Disconnect power to the NGC system before inserting, removing, or moving modules. No user-serviceable parts are inside any component unless noted in this manual. Refer servicing questions to Bio-Rad service personnel.

## Regulatory Information

The NGC instrument has been tested and found to be in compliance with all applicable requirements of the following safety and electromagnetic compliance standards. The NGC instrument is labeled with the following compliance marks.

### Safety Compliance

CE Mark:

- EN61010-1 Electrical Equipment for Measurement, Control, and Laboratory Use
- IEC 61010-1 Safety Requirements for Measurement, Control, and Laboratory Use, Part 1: General Requirements

cTUVus Mark:

- UL STD No. 61010-1 Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements
- CAN/CSA C22.2 No. 61010-1-12 Safety Requirements for Measurement, Control, and Laboratory Use, Part 1: General Requirements (includes Amendment 1)

Products with these safety compliance marks are safe to use when operated in accordance with the instruction manual. This does not extend to accessories with no marks, even when used with this unit.

### Electromagnetic Compatibility (EMC)

CE Mark:

- EN61326 Class A Electrical Equipment for Measurement, Control, and Laboratory Use, General Requirements

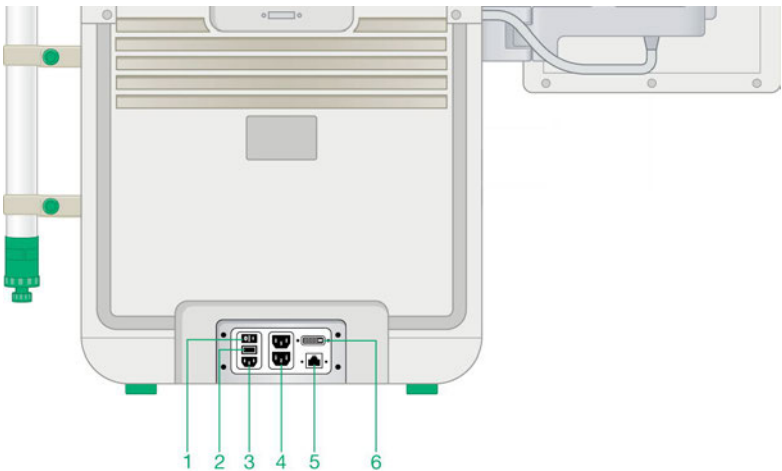
The NGC instrument is designed to operate in a controlled electromagnetic environment. Do not use radio transmitters within 10 ft (3 m) of the instrument.

Connecting the Power and Communication Cables

Connecting the Power and Communication Cables

The power sockets and communication ports for the NGC system are located on the back of the instrument. Because the back of the instrument will be very close to the back of the standard cold cabinet, it is recommended that you connect the power and communication cables before lifting the instrument into the cabinet.

**Note:** The Cat 6 ethernet cable to connect the NGC instrument to the computer running ChromLab software is approximately 10' (3.0 m) in length.



LEGEND					
1	Power on/off switch	2	Fuse cover		
3	Power inlet port	4	Power outlet ports		
5	Ethernet connection port	6	Touch screen connection port		

3 | Setting Up NGC Chromatography Systems

**To connect the power and communication cables**

1. If you have not already done so, insert the end of the touch screen cable into the touch screen connection port on the back of the instrument.
2. Insert the Cat 6 (or higher) cable into the ethernet port on the back of the instrument.
3. (Optional) Connect the power cords for any peripheral instruments into the power outlet ports.
4. Connect the power cable to the power inlet port.
5. If installing the NGC instrument into a standard cold cabinet, direct the following cables through the access port on the side of the cabinet:
  - Touch screen cable
  - Ethernet cable
  - Power cable (if your cabinet does not have a power outlet)
6. Press the I/O power switch to the On position.



**Caution:** The weight of the NGC instrument varies from moderate to heavy depending on the system. Take care when lifting the instrument into the cold cabinet. To reduce the risk of personal injury or damage to the instrument, three or more people should perform this task.

7. If installing the NGC instrument into a standard cold cabinet:
  - a. Lift the instrument into position.
  - b. Connect the power cable to the power outlet.

Connecting the NGC System to the ChromLab Computer

## Connecting the NGC System to the ChromLab Computer

**Note:** Ensure that the ChromLab computer and the NGC instrument are powered off before beginning this task.

You can connect the NGC system to the ChromLab computer in one of two ways:

- Direct cable connection using a Cat 6 ethernet cable
- Network connection through your network infrastructure

### Establishing a Direct Cable Connection

**Tip:** You should have already inserted the Cat 6 ethernet cable into the port at the back of the NGC instrument. See [To connect the power and communication cables on page 78](#).

If the ChromLab computer has two network adapters and you are establishing a direct connection to the NGC instrument, you can use the second adapter to connect the computer to your company's network.

#### To establish a direct cable connection

- Insert the loose end of the Cat 6 ethernet cable into one of the ethernet connection ports on the computer on which you plan to install ChromLab.

**Note:** The network adapter that is used to connect the NGC instrument needs to be configured to use TCP/IP 4.0 with dynamic host configuration protocol (DHCP). For information about configuring the network adapter, see [Configuring the Network Adapter for Direct Connection on page 158](#).



## Establishing a Network Connection

When establishing a connection between the NGC system and the ChromLab computer through your network infrastructure, ensure that they are both on the same subnet. A DHCP server is required so that the system receives an IP address.

**Note:** The DHCP server should be configured to always assign the same IP address to the system. See your network administrator for more information.

**Tip:** You should have already inserted the Cat 6 ethernet cable into the port at the back of the NGC instrument. See [To connect the power and communication cables on page 78](#).

### To establish a network connection

- Insert the loose end of the Cat 6 ethernet cable into the network connection router or hub.



**Bio-Rad  
Laboratories, Inc.**

*Life Science  
Group*

**Web site** *bio-rad.com* **USA** 1 800 424 6723 **Australia** 61 2 9914 2800 **Austria** 43 01 877 89019 **Belgium** 32 03 710 53 00  
**Brazil** 55 11 3065 7550 **Canada** 1 905 364 3435 **China** 86 21 6169 8500 **Czech Republic** 36 01 459 6192  
**Denmark** 45 04 452 10 00 **Finland** 35 08 980 422 00 **France** 33 01 479 593 00 **Germany** 49 089 3188 4393  
**Hong Kong** 852 2789 3300 **Hungary** 36 01 459 6190 **India** 91 124 4029300 **Israel** 972 03 963 6050 **Italy** 39 02 49486600  
**Japan** 81 3 6361 7000 **Korea** 82 2 3473 4460 **Mexico** 52 555 488 7670 **The Netherlands** 310 318 540 666  
**New Zealand** 64 9 415 2280 **Norway** 47 0 233 841 30 **Poland** 36 01 459 6191 **Portugal** 351 21 4727717  
**Russia** 7 495 721 14 04 **Singapore** 65 6415 3188 **South Africa** 36 01 459 6193 **Spain** 34 091 49 06 580  
**Sweden** 46 08 555 127 00 **Switzerland** 41 0617 17 9555 **Taiwan** 886 2 2578 7189 **Thailand** 66 2 651 8311  
**United Arab Emirates** 971 4 8187300 **United Kingdom** 44 01923 47 1301



# **EXHIBIT 32**



US009709589B2

(12) **United States Patent**  
**Blomberg et al.**

(10) **Patent No.:** **US 9,709,589 B2**

(45) **Date of Patent:** **\*Jul. 18, 2017**

(54) **AUTOMATED FLUID HANDLING SYSTEM**

(71) Applicant: **GE HEALTHCARE BIO-SCIENCES AB**, Uppsala (SE)

(72) Inventors: **Johan Blomberg**, Uppsala (SE); **Mats Lundkvist**, Uppsala (SE)

(73) Assignee: **GE HEALTHCARE BIO-SCIENCES AB**, Uppsala (SE)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/165,876**

(22) Filed: **May 26, 2016**

(65) **Prior Publication Data**

US 2016/0274070 A1 Sep. 22, 2016

**Related U.S. Application Data**

(63) Continuation of application No. 14/463,039, filed on Aug. 19, 2014, which is a continuation of application (Continued)

(30) **Foreign Application Priority Data**

Jun. 9, 2009 (SE) ..... 0950431

(51) **Int. Cl.**  
**B01D 35/00** (2006.01)  
**G01N 35/10** (2006.01)  
(Continued)

(52) **U.S. Cl.**  
CPC ..... **G01N 35/1097** (2013.01); **B01D 15/10** (2013.01); **B01D 29/60** (2013.01);  
(Continued)

(58) **Field of Classification Search**

None

See application file for complete search history.

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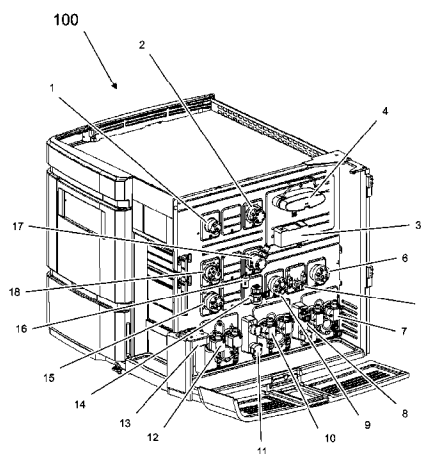
*Primary Examiner* — Richard Gurtowski

(74) *Attorney, Agent, or Firm* — Arent Fox LLP

(57) **ABSTRACT**

Automated fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components with an external fluidics section and an internal non fluidics section, and wherein the housing comprises a liquid handling panel with two or more of component positions for receiving said interchangeable modular components such that the external fluidics section is separated from the non fluidics section by the liquid handling panel.

**30 Claims, 10 Drawing Sheets**



Shinoff  
7/22/2020

**EX 119**

## US 9,709,589 B2

Page 2

## Related U.S. Application Data

No. 13/376,929, filed as application No. PCT/SE2010/050624 on Jun. 4, 2010, now Pat. No. 8,821,718.

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**G01N 30/88** (2006.01)  
**B01D 29/60** (2006.01)  
**G01N 30/24** (2006.01)  
**G01N 30/38** (2006.01)  
**B01D 15/08** (2006.01)  
**B01D 17/12** (2006.01)  
**G01N 35/00** (2006.01)  
**G01N 30/02** (2006.01)

## (52) U.S. Cl.

CPC ..... **G01N 30/24** (2013.01); **G01N 30/38** (2013.01); **G01N 30/88** (2013.01); **B01D 15/08** (2013.01); **B01D 17/12** (2013.01); **B01D 2201/54** (2013.01); **G01N 2030/027** (2013.01); **G01N 2030/8804** (2013.01); **G01N 2030/8881** (2013.01); **G01N 2035/00326** (2013.01); **Y10T 137/6416** (2015.04); **Y10T 137/6525** (2015.04); **Y10T 137/6851** (2015.04); **Y10T 137/85986** (2015.04); **Y10T 137/87885** (2015.04)

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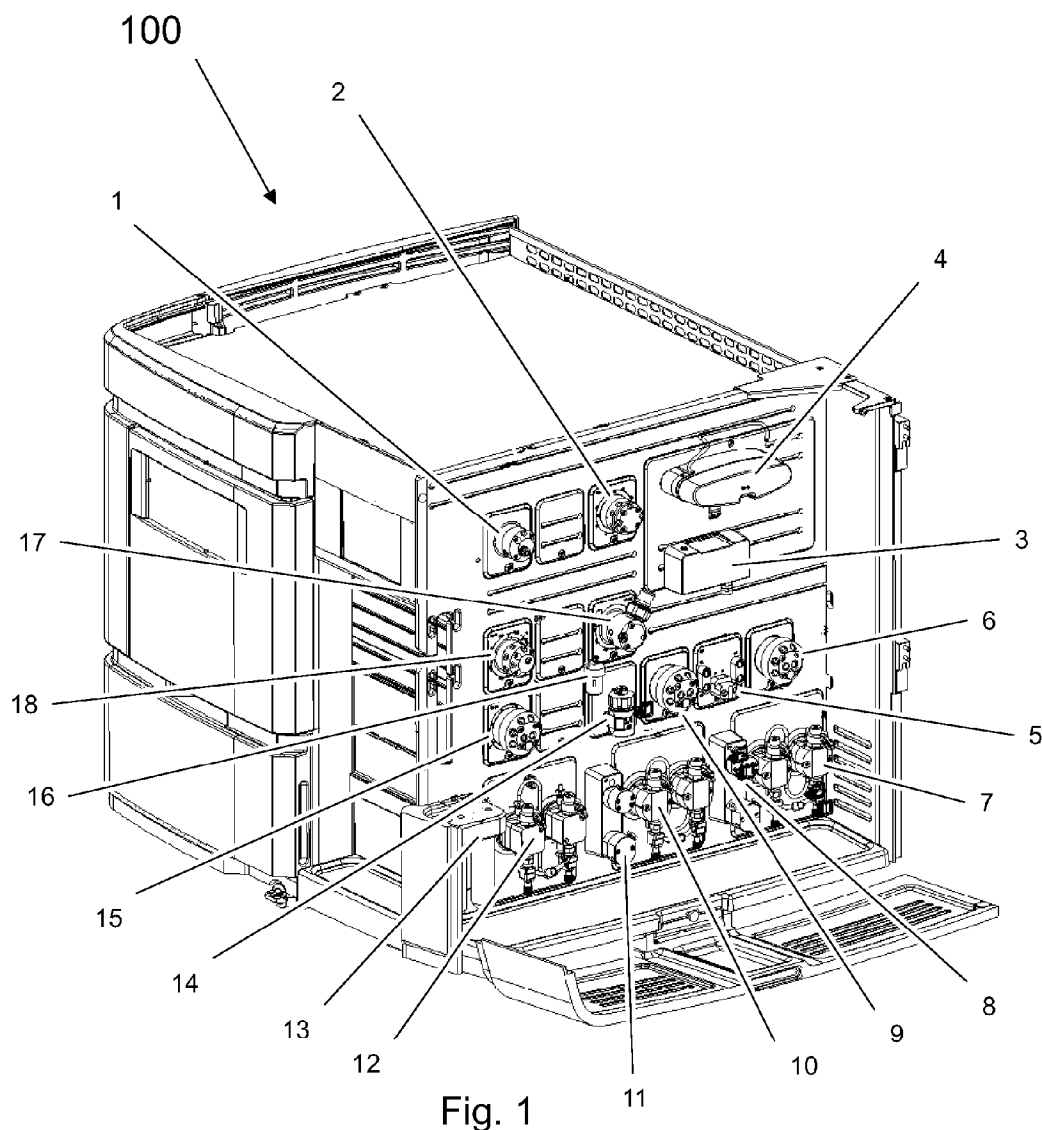
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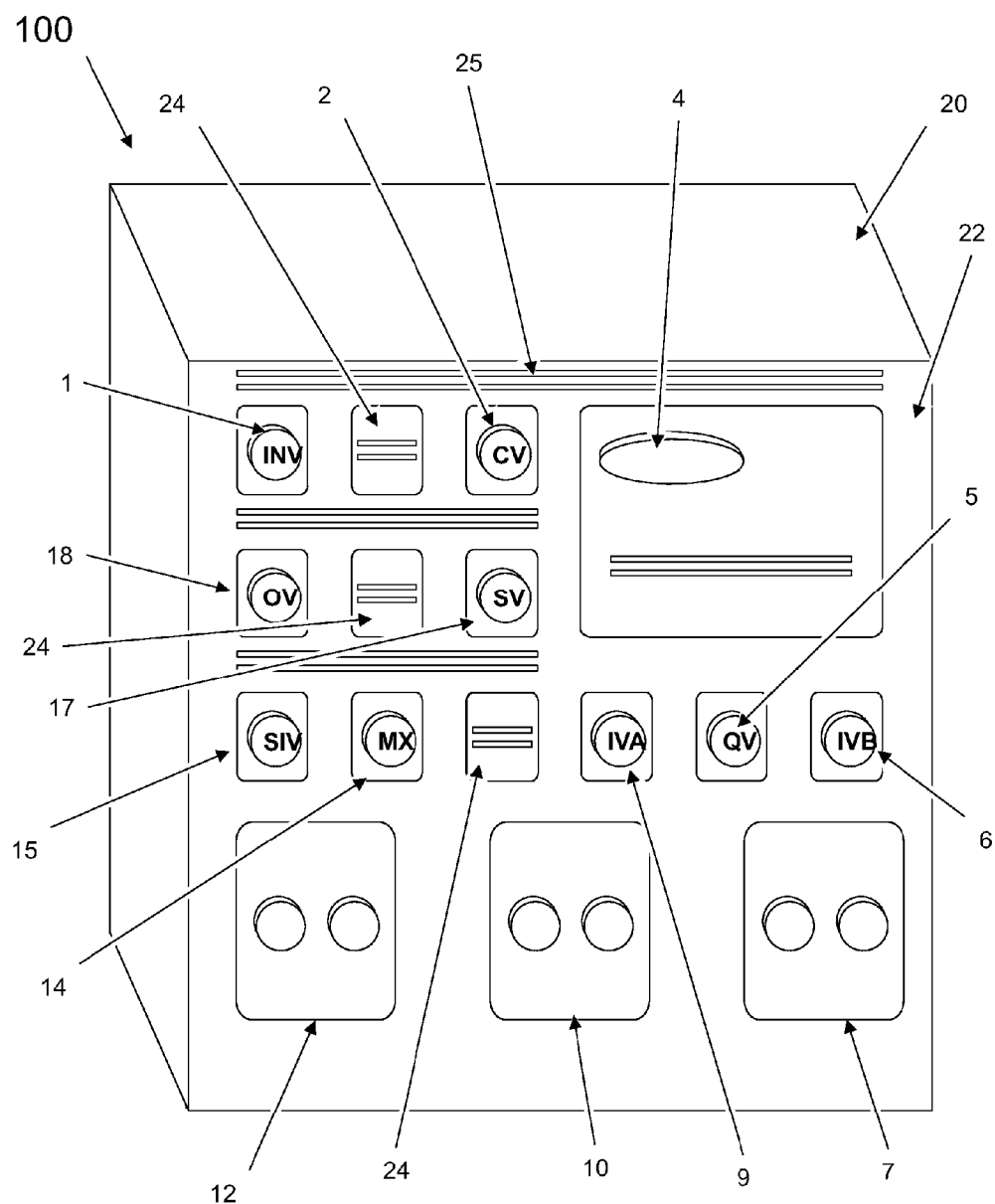


Fig. 2

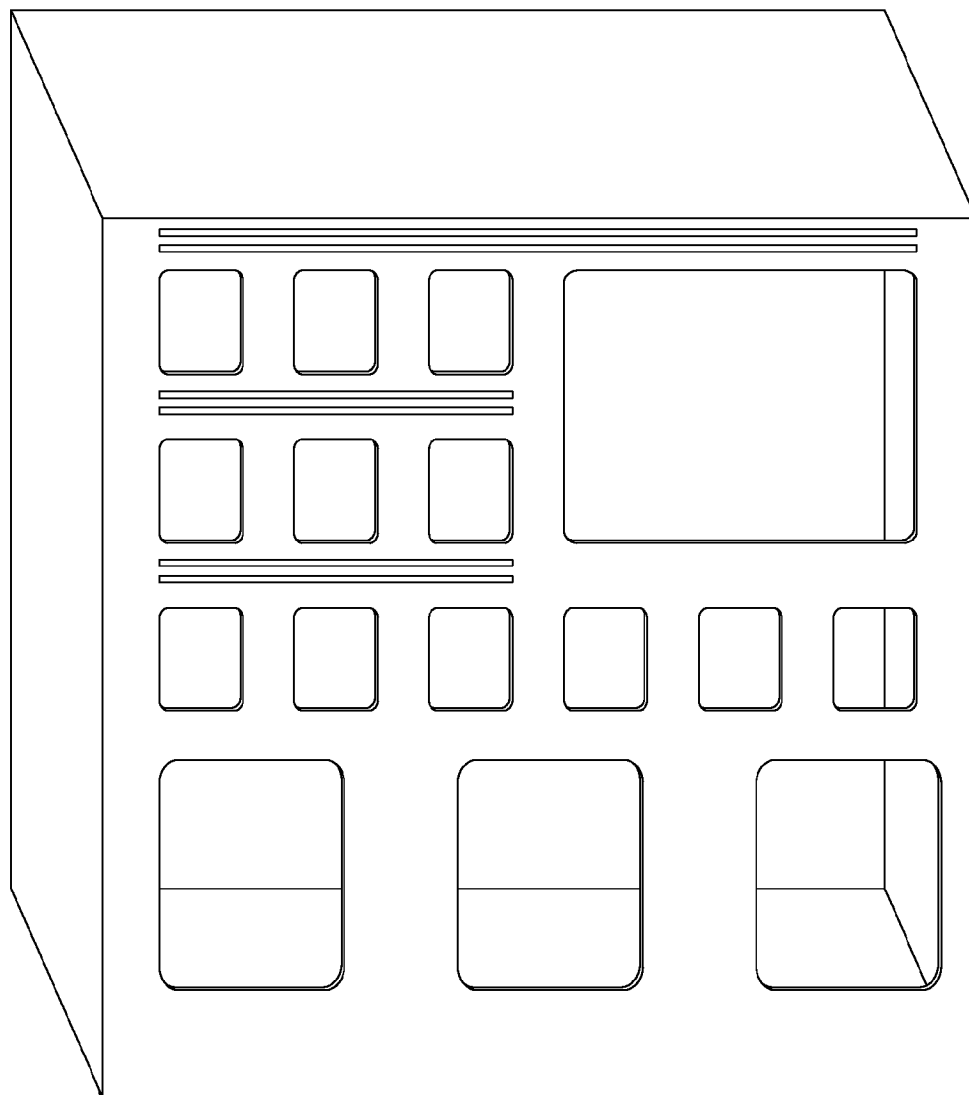


**U.S. Patent**

**Jul. 18, 2017**

**Sheet 3 of 10**

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**Fig. 3**

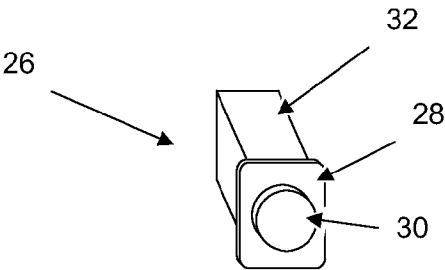


Fig. 4a

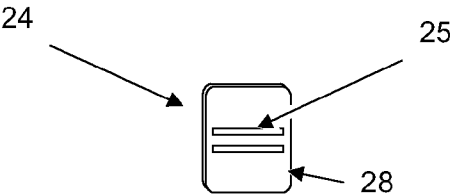


Fig. 4b

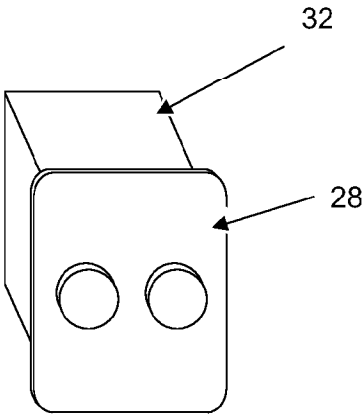


Fig. 4c

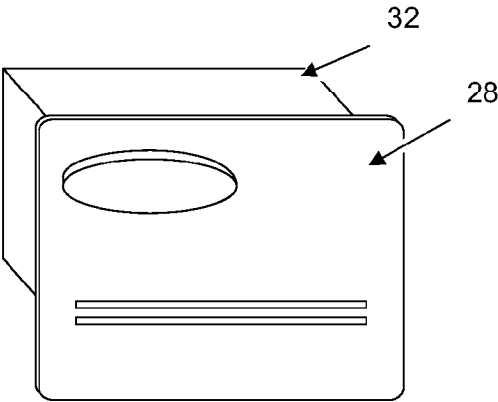


Fig. 4d

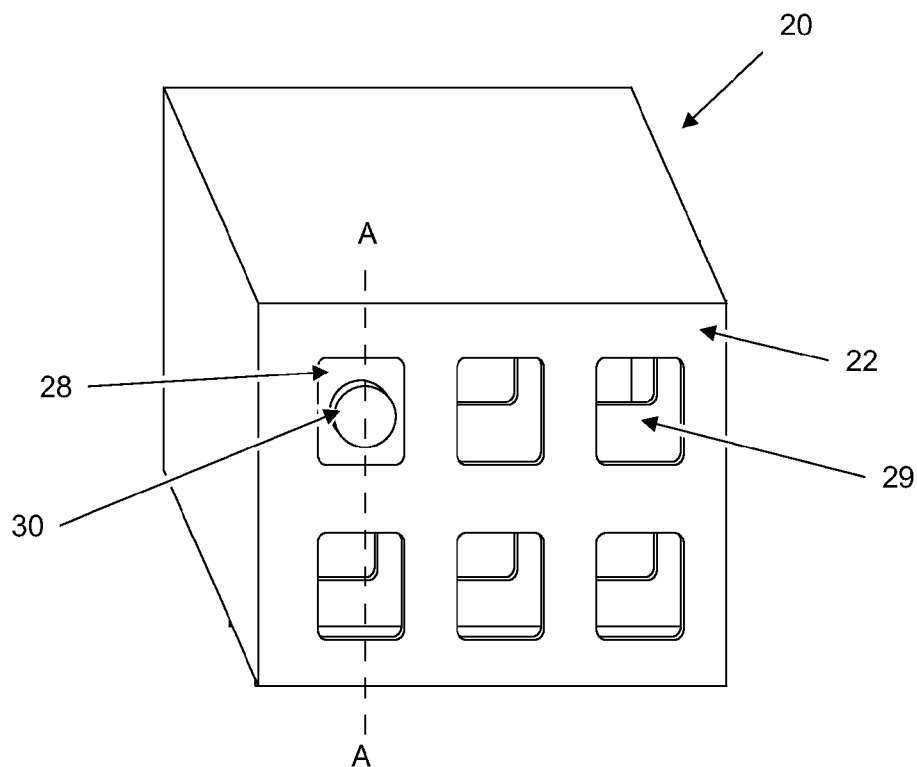


Fig. 5a

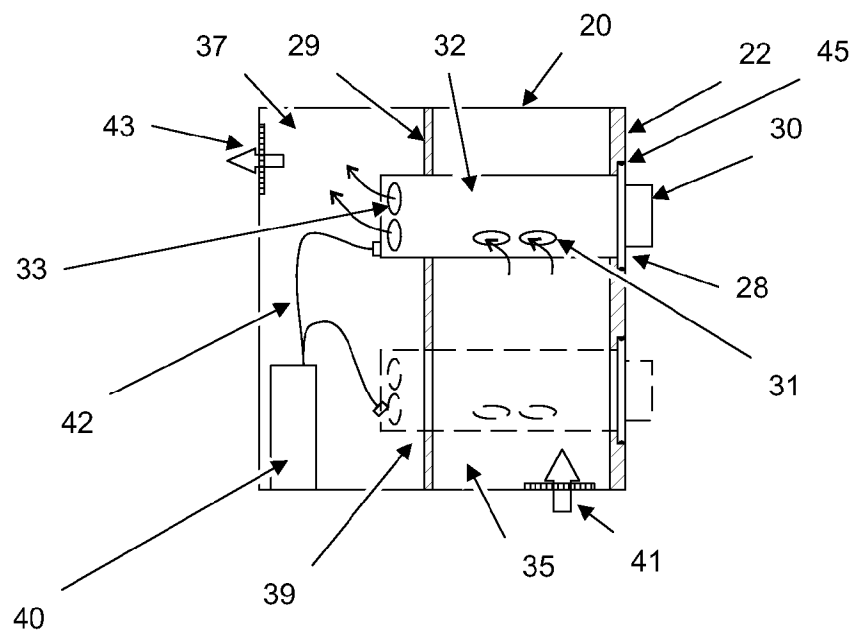
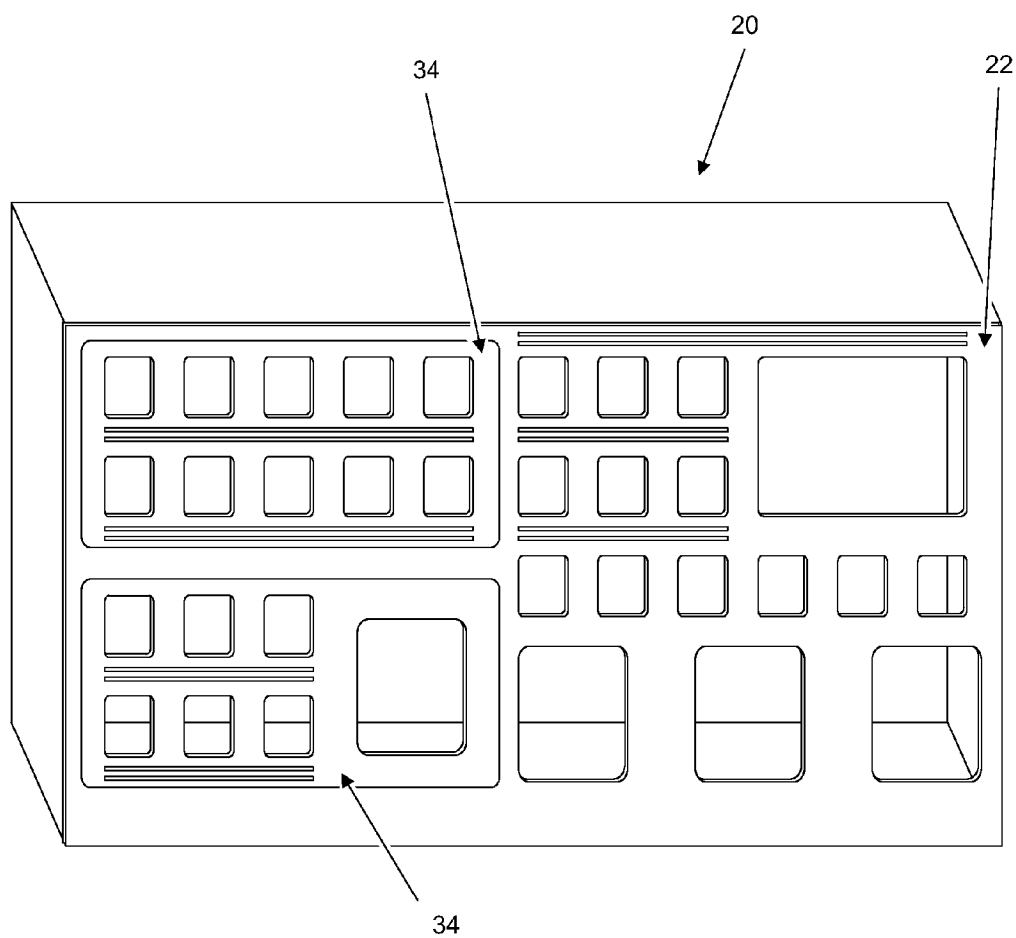


Fig. 5b



**Fig. 6**

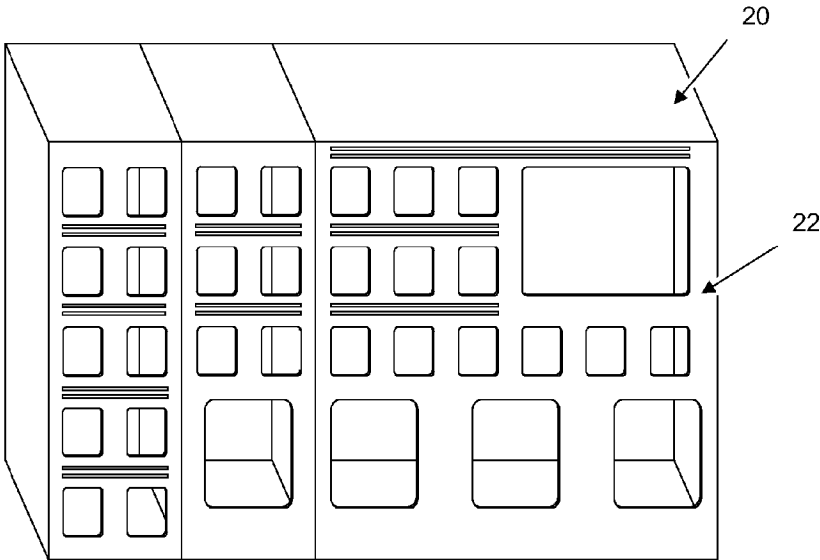


Fig. 7a

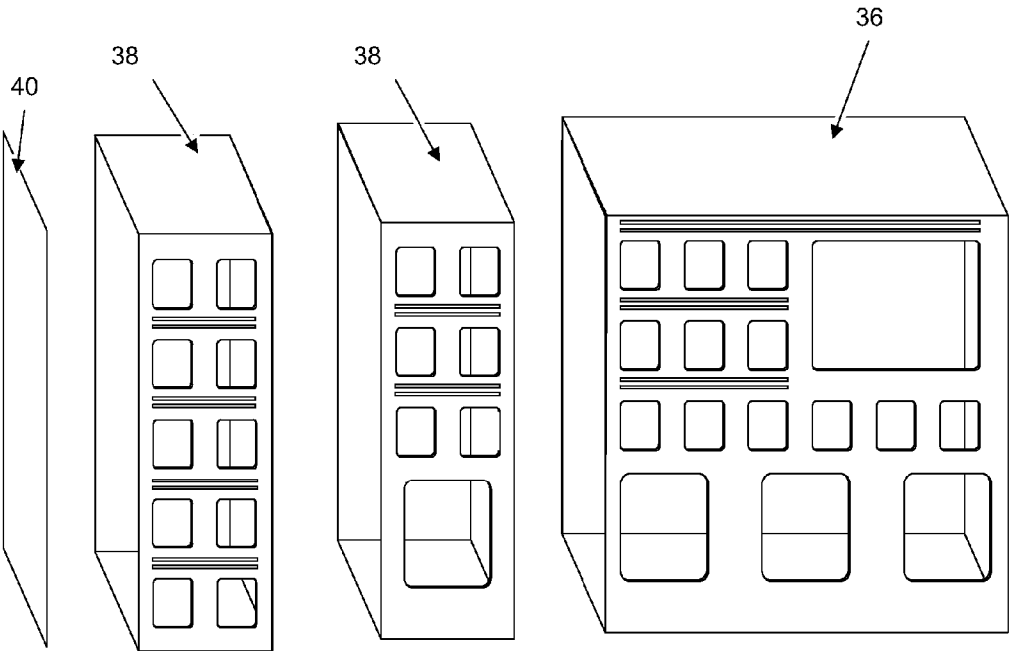
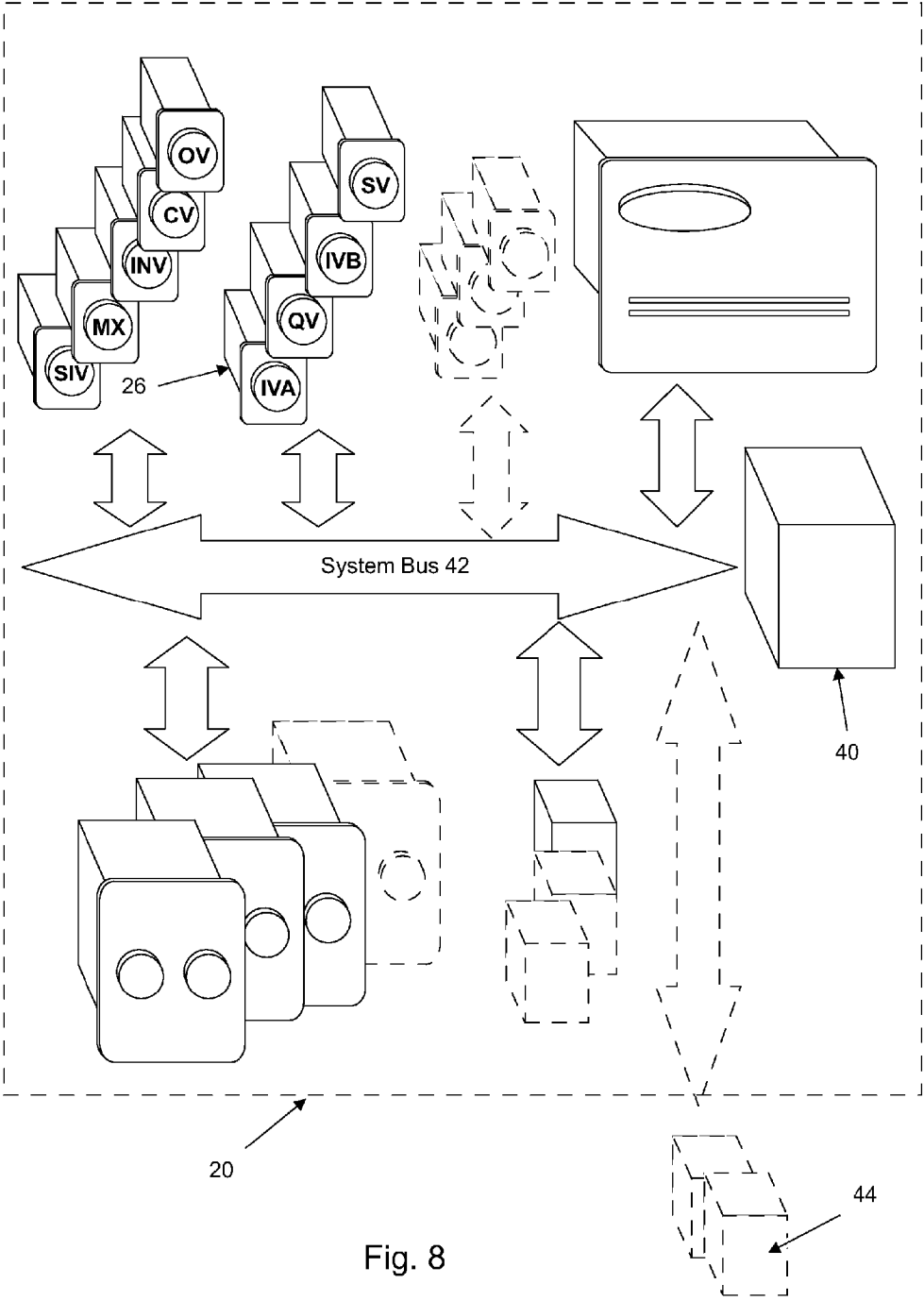


Fig. 7b



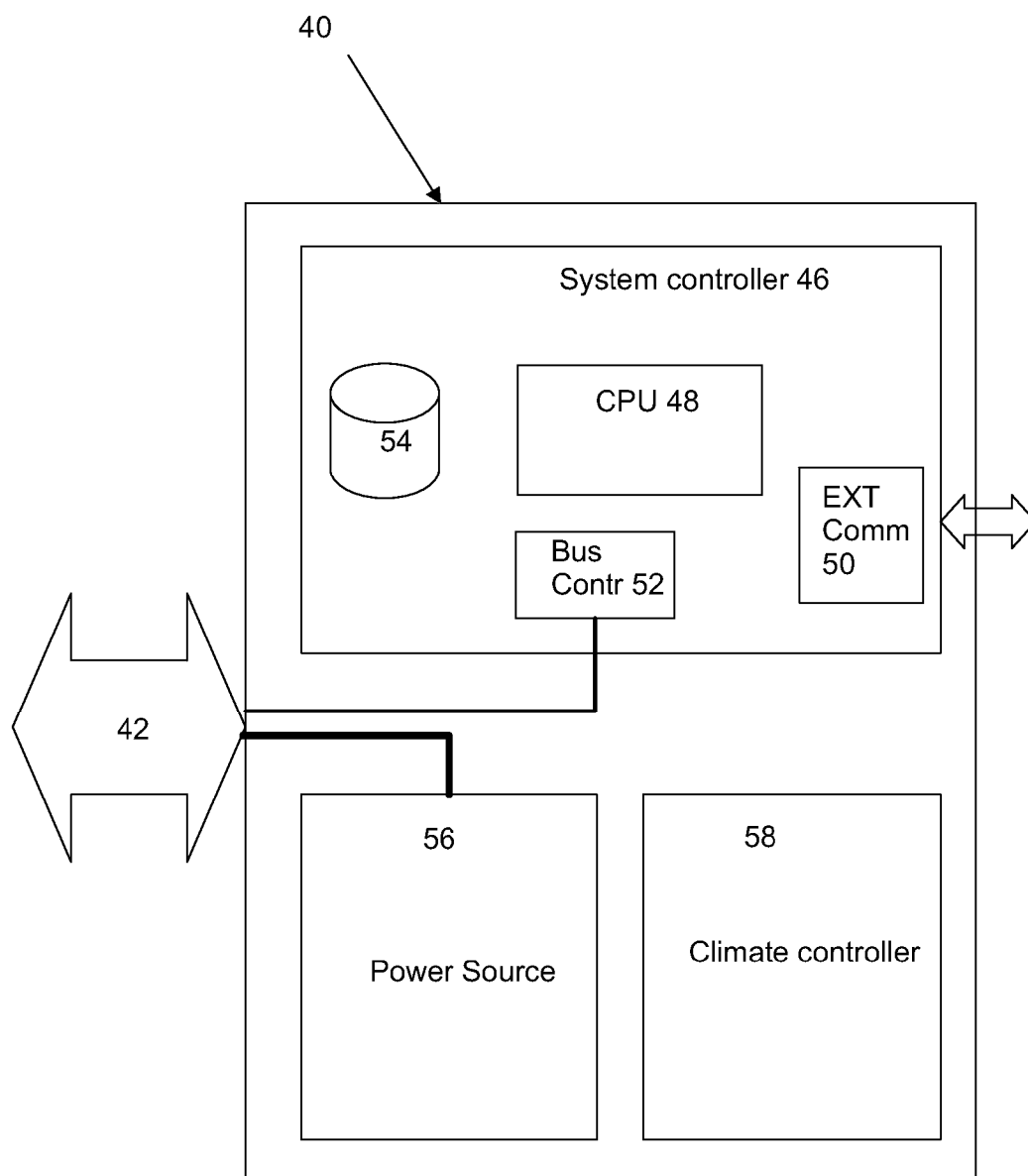


Fig. 9

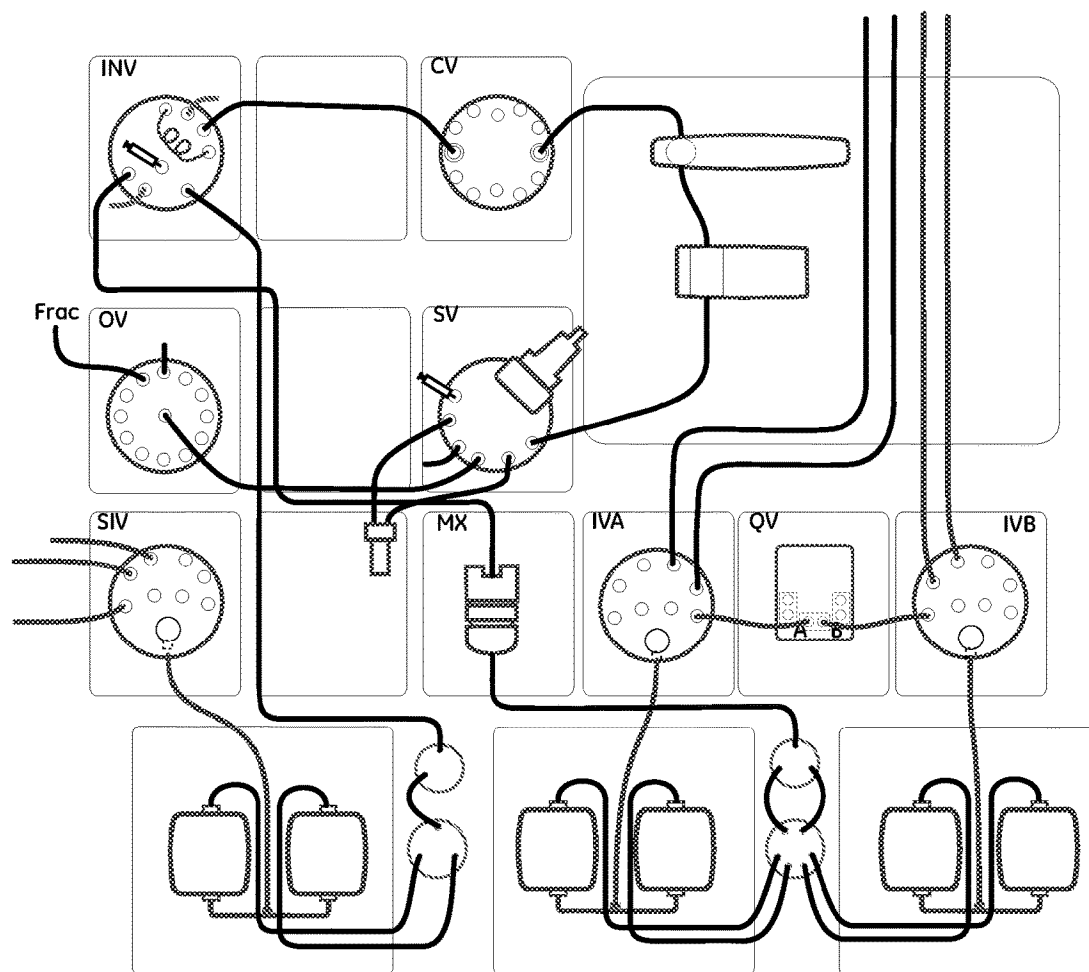


Fig. 10



US 9,709,589 B2

1

**AUTOMATED FLUID HANDLING SYSTEM****CROSS REFERENCE TO RELATED APPLICATION**

This application is a Continuation of U.S. patent application Ser. No. 14/463,039 filed Aug. 19, 2014 which is a Continuation of U.S. patent application Ser. No. 13/376,929 filed Dec. 8, 2011 which is a 35 U.S.C. 371 National Phase of International Patent Application No. PCT/SE2010/050624 filed Jun. 4, 2010 which claims priority to Swedish Patent Application No. 0950431-7 filed Jun. 9, 2009, the disclosure of these prior applications are hereby incorporated in their entirety by reference

**BACKGROUND OF THE INVENTION**

The present invention relates to the art of fluid handling system systems, and in particular to an automated fluid handling system that is highly flexible and configurable. The fluid handling system may e.g. be a liquid chromatography system, a filtration system, a chemical synthesis system or the like.

There is a large range of fluid handling systems e.g. in laboratories. Such systems comprise a number of fluid handling units, e.g. one or more pumps, valves, mixers, sensor units etc of different types. Said fluid handling units are interconnected by fluid conduits in the form of, rigid or flexible tubes or the like. Even though some systems may be designed for a specific type of application with a specific flow path, there often exists a need for flexibility and ability to alter or optimize the fluid flow path of the system. Moreover, upgrading is often restricted to specific kits provided by the manufacturer, and upgrade kits often is supplied as external add-on equipment to be arranged besides the original system, thus enlarging the foot print of the system and that need to be connected to the system both fluidically and electrically (i.e. to a system control bus or the like). Moreover, replacement of defect fluid handling units is a time consuming and delicate task.

One type of liquid handling system is liquid chromatography systems which is a standard method in laboratories, and there are a broad range of liquid chromatography systems available on the market. Common to most of the present systems is the lack of flexibility in adapting the instrument to a variety of different applications.

**SUMMARY OF THE INVENTION**

The object of the invention is to provide a new fluid handling system, which system overcomes one or more drawbacks of the prior art. This is achieved by the fluid handling system as defined in the independent claims.

One advantage with such a fluid handling systems is that the system may easily be upgraded without need for add-on equipment, and that the flow path may be easily optimized for new experimental setups.

Embodiments of the invention are defined in the dependent claims.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The invention will be described in detail below with reference to the drawings, in which

FIG. 1 shows one embodiment of a fluid handling system in the form of a liquid chromatography system, according to the present invention.

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FIG. 2 is a schematic illustration of a housing with a liquid handling panel of the fluid handling system of FIG. 1.

FIG. 3 is a schematic illustration of the housing with the liquid handling panel of FIG. 2 with the modular components of the fluid handling system removed.

FIGS. 4a to 4d are schematic illustrations of examples of component modules of the fluid handling system removed.

FIGS. 5a and 5b show a schematic embodiment of an automated fluid handling system.

FIG. 6 is a schematic illustration of an embodiment of a housing with a modular liquid handling panel with the modular components of the fluid handling system removed.

FIGS. 7a and 7b are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with the modular components of the fluid handling system removed.

FIG. 8 is a schematic illustration of an embodiment of the system architecture of one embodiment of a fluid handling system according to the present invention.

FIG. 9 is a schematic illustration of an embodiment of a master control unit of one embodiment of a fluid handling system according to the present invention.

FIG. 10 is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel for the liquid chromatography system of FIG. 1.

**DETAILED DESCRIPTION OF THE INVENTION**

According to one embodiment, there is provided an automated fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components with an external fluidics section and an internal non fluidics section, and wherein the housing comprises a liquid handling panel with two or more of component positions for receiving said interchangeable modular components such that the external fluidics section is separated from the non fluidics section by the liquid handling panel.

According to another embodiment, there is provided a fluid handling system in the form of a liquid chromatography system comprising a housing, two or more high pressure pumps, at least one sensor unit and a plurality of fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components and the housing comprises a liquid handling panel with a plurality of component positions for receiving said modular components.

FIG. 1 shows one embodiment of an automated fluid handling system modular in the form of a liquid chromatography system, with a plurality of interchangeable modular components arranged in a liquid handling panel wherein the reference numbers denotes:

1. Injection valve
2. Column valve with integrated pressure sensors
3. Conductivity monitor
4. UV monitor
5. Quaternary valve
6. Inlet valve B with integrated air sensor
7. System pump
8. Pressure monitor, system pump
9. Inlet valve A with integrated air sensor
10. System pump
11. Pressure monitor, sample pump
12. Sample pump
13. Rinsing system

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- 14. Mixer with online filter
- 15. Sample inlet valve with integrated air sensor
- 16. Flow restrictor
- 17. pH valve
- 18. Outlet valve

The disclosed embodiment is supplied with three high precision pumps 7, 10, 12. There are two System pumps 7, 10, System pump A 10 and System pump B 7, and one Sample pump 12. The System pumps 7, 10 may be used individually, or in combination to generate isocratic or gradient elution in purification methods. The Sample pump 12 is dedicated for direct loading of sample onto a column, or for filling of sample loops.

#### Function of the Pumps

Each pump module consists of two pump heads (not shown). The individual heads are identical but actuated in opposite phase to each other by individual stepper motors, controlled by a microprocessor. The two pistons and pump heads work alternately to give a continuous, low pulsation, liquid delivery. The flow rate of the two System pumps may be varied between about 0.001 ml/min and 25.000 ml/min and the maximum operating pressure is about 20 MPa. The flow rate of the Sample pump may e.g. be varied between 0.01 and 25 ml/min and according to one embodiment the maximum operating pressure is 10 MPa.

According to one embodiment, the plurality of fluid control valves of at least two different configurations are valves of rotary type. Such a motorized rotary valve may consist of a Valve head with a number of defined bores with channels to the inlet and outlet ports of the valve. The Rotary disc, mounted on the motor, has a number of defined channels. The pattern of channels of the Rotary disc together with the pattern and location of the ports of the Valve head, define the flow path and function of each type of valve. When the Rotary disc turns, the flow path in the valve changes.

One embodiment of fluid control valves are Inlet valves A and B (9, 6 respectively) that are used to select which buffers or samples to use in a run, and Sample inlet valve 15 that is located before Sample pump 12. Inlet valve A 9 is located before System pump A 10, Inlet valve B 6 is located before System pump B 10, and Sample inlet valve 15 is located before Sample pump 12. Inlet valve A and Inlet valve B are connected to another embodiment of a fluid control valve in the form of a Quaternary valve 5. The Quaternary valve is used for automatic buffer preparation, and for formation of quaternary gradients. The number of inlets can be increased by installing component modules with extra inlet valves. Inlet valve A and Inlet valve B enable automatic changing between different buffers and wash solutions, and can be used to generate gradients by mixing buffer A and buffer B. The air sensors integrated in Inlet valve A and Inlet valve B can be used to prevent introduction of air into the pumps and columns.

The Quaternary valve is used for automatic mixing of four different solutions. The Quaternary valve opens one inlet port at a time, and the different solutions are mixed in a Mixer 14 to form the desired buffer. The opening time in the switching valve is controlled by the system. The volume for each inlet port opening increases stepwise when the flow increases. To obtain a homogeneous buffer composition, one has to make sure to use a mixer chamber volume suitable for the flow rate of the method.

The Quaternary valve can be used to create a gradient using four different solutions simultaneously in any combination. The percentage of each solution is controlled by instructions in the method. It is possible to form gradients

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that changes the percentage of two, three or four solutions linearly over time. This is useful when advanced methods are developed.

The Sample inlet valve 15 enables automatic loading of different samples when using the Sample pump 12 to inject sample directly onto the column or to fill a sample loop. The Sample inlet valve has an inlet dedicated for buffer. This Buffer inlet is used in methods to fill the Sample pump with solution before sample is introduced. The Buffer inlet is also used to wash the Sample pump with buffer between runs. The air sensor integrated in the Sample inlet valve is e.g. used when sample is applied from a vessel onto a column by selecting Inject all sample using air sensor in the Sample application phase of a method. This function uses the Buffer inlet is used to finalize sample injection and to remove air from the Sample pump.

Still another embodiment of fluid control valve may be an Injection valve 1, which is used to direct sample onto the column. The valve enables usage of a number of different sample application techniques. A sample loop can be connected to the Injection valve and filled either automatically using the Sample pump or manually using a syringe. The sample can also be injected directly onto the column using the Sample pump.

Still another embodiment of fluid control valve may be a Column valve 2 that is used for connection of columns to the system, and to direct the flow onto the column. Up to five columns can be connected to the disclosed embodiment of said valve simultaneously. The valve also has a built-in bypass capillary that enables bypassing of connected columns.

The number of column positions can be increased by installing an extra Column valve. Both top and bottom of each column shall be connected to the Column valve. The top of the column shall be connected to one of the A ports (e.g., 1A), and the bottom of the column shall be connected to the corresponding B port (e.g., 1B). The flow direction can be set either from the top of the column to the bottom of the column, Down flow, or from the bottom of the column to the top of the column, Up flow. In the default flow path of the Column valve the columns are bypassed. Pressure monitors that measures the actual pressure over the column are integrated into the inlet and outlet ports of the Column valve.

Still another embodiment of fluid control valve may be a pH valve 17 that has an integrated flow cell where a pH electrode can be installed. This enables in-line monitoring of pH during the run. A flow restrictor is connected to the pH valve and can be included in the flow path to generate a backpressure high enough to prevent formation of air bubbles in the UV flow cell. The pH valve is used to direct the flow to the pH electrode and to the flow restrictor, or to bypass one or both.

Still another embodiment of fluid control valve may be an Outlet valve 18 that is used to direct the flow to a Fraction collector (not shown), to any of e.g. 10 outlet ports, or to waste. The number of outlets can be increased by installing an extra Outlet valve.

A Mixer 14 may e.g. be located after System pump A and System pump B and before the Injection valve. The purpose of the Mixer is to make sure that the buffers from the System pumps are mixed to give a homogenous buffer composition. The Mixer has a built-in filter that prevents impurities from entering the flow path.

To fulfill a desired purpose, with the disclosed liquid chromatography system it is possible to adapt and extend the flow path in a simple and a flexible way. Up to three extra

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fluid control valves or the like can be installed using the free valve positions. Dummy modules are installed in these positions at delivery. To obtain an optional flow path, it is also possible to move the standard fluid control valves to other positions. There are also two types of extra air sensors available which can be installed before Sample inlet valve or after Injection valve.

In the configuration disclosed in FIG. 1, 7 inlets are available for each inlet valve. To increase the number of inlets, an extra inlet valve can be installed which increases the number of inlets to 14 for one of the valves. This optional configuration can be convenient for example when a larger number of samples will be used. There is also a general type of inlet valve, Valve X, which can be used to increase the number of inlets to for example the Quaternary valve.

In the configuration disclosed in FIG. 1 with one column valve, 5 column positions are available. To increase the number of column positions to 10, an additional column valve can be installed in the instrument. An application can be to evaluate a number of different columns in method optimization.

In the configuration disclosed in FIG. 1 with one outlet valve, 10 outlet positions are available. To increase the number of outlets, one or two extra outlet valves can be connected, adding up to a total of 21 or 32 outlet positions. This optional configuration is convenient when collecting a number of large fractions outside the fraction collector.

Optional modules are easy to install in the disclosed modular liquid chromatography system. The dummy module is removed with a hexagon wrench and a bus cable is disconnected. The bus cable is connected to the optional fluid control valve or the like which is assembled in the instrument. The module is then added to the System properties in the control software. The available optional modules may e.g. be pre-configured to give the desired function. However, the function of a valve may e.g. be changed by changing the Node ID.

FIG. 2 is a schematic illustration of a housing 20 with a liquid handling panel 22 of the fluid handling system in the form of a modular liquid chromatography system 100 of FIG. 1. In FIG. 2 some components have been removed for clarity reasons. In the disclosed configuration, as disclosed in detail above, the modular liquid chromatography system 100 comprises a plurality of fluid control valves in the form of: Injection valve 1, Column valve 2, Quaternary valve 5, Inlet valve B 6, Inlet valve A 9, Sample inlet valve 15, pH valve 17, and Outlet valve 18. The chromatography system 100 further comprises UV monitor 4, System pump B 7, System pump A 10, Sample pump 12, Mixer 14, and three Dummy modules 24. According to one embodiment, all liquid handling components and sensors arranged at the liquid handling panel 22 are designed to be readily interchangeable. The interchangeability provides improved service and upgrade possibilities and also a possibility to customize the positions of the respective liquid handling components, such as the fluid control valves, e.g. in order to optimize the fluid path for a specific experimental setup. As is illustrated in FIG. 2, there are three large component positions e.g. for pump modules, one UV-sensor position and 9 standard component positions, e.g. for fluid control valves or the like. The component positions are given a standardized size and shape to provide simple interchangeability. According to one embodiment, each modular component is retained in a mating component position by a single screw, and it is connected to the master control unit by a single bus cable providing both communication and system power to each component. FIG. 3 is a schematic

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illustration of the housing with the liquid handling panel of FIG. 2 with the modular components of the liquid chromatography system removed.

FIGS. 4a to 4d are schematic illustrations of examples of fluid handling units in the form of modular component of the fluid handling system removed. FIG. 4a shows a standard interchangeable modular component 26, e.g. a fluid control valve or the like. The standard component module 26 comprises a panel member 28, an external fluidics section 30 and an internal non-fluidics section 32. According to one embodiment, the panel member 28 essentially separates the fluidics in the external fluidics section 30 from electronics and control means in the internal non-fluidics section 32.

FIG. 4b shows a Dummy module 24, which is intended to be placed in non used standard component positions. In the disclosed embodiment, the Dummy modules are provided with mounting grooves for attachment of accessories to the system. In the disclosed embodiment the dummy module is shown as a panel member 28 without any internal section. FIGS. 4c and 4d shows a pump module and an UV-module, respectively, each having an external fluidics section 30 and an internal non-fluidics section 32.

As is disclosed in FIGS. 4a to 4d, the interchangeable modular components 26 comprises a panel member arranged to separate the fluidics section from the non fluidics section and for attachment to a component position in the liquid handling panel. Said panel attachment member may be arranged so that all fluid connections of said modular component are arranged on a wet side of the panel attachment member separating them from electrical components that are arranged on a dry side thereof, hence providing a high degree of liquid resistance at the external part of the fluid handling panel, and so that the liquid resistance requirements for the internal sections may be somewhat lightened. According to one embodiment, the interchangeable modular components are sealed against the liquid handling panel by a sealing member. According to another embodiment, not shown, the modular component does not comprise any panel member, but there is provided a suitable sealing arrangement between the component position openings of the liquid handling panel and the external surface of the interchangeable modular components 26. In the disclosed embodiments, the component position openings of the liquid handling panel and the interchangeable modular components 26 are shown to have an essentially rectangular crosssectional shape, but other shapes may be equally applicable. According to one embodiment, there is provided a general fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components as is schematically disclosed in FIG. 5a. As discussed above such a system may be configured for essentially any type of automated liquid handling operations provided that suitable fluid handling units are provided as interchangeable modular components for the system. According to one embodiment there is provided an automated fluid handling system comprising at least one fluid pump, at least one sensor unit and two or more fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components.

The liquid handling panel 22 of the fluid handling system may e.g. be designed in any suitable manner to allow the modular components to be arranged in an efficient manner.

FIGS. 5a and 5b shows a schematic embodiment of an automated fluid handling system wherein the housing 20 comprises an internal climate panel 29 arranged at a distance behind the liquid handling panel 22 defining an air inlet

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compartment 35 and air outlet compartment 37 in the housing 20, the climate panel 29 being provided with complementary component positions 39 for receiving the internal non fluidics section 32 of the interchangeable modular components 26, and wherein the non-fluidics section 32 of at least one interchangeable modular component is provided with one or more air inlet openings 31 located in the air inlet compartment 35 and one or more air outlet openings 33 located in the air outlet compartment 37 when the interchangeable modular component arranged in position in the component position. FIG. 5b shows the fluid handling system of FIG. 5a in a schematic cross sectional view. As is indicated by inlet vent 41 and outlet vent 43, air for cooling interchangeable modular components 26 provided with air inlet and outlet openings 31, 33 is preferably arranged to enter the air inlet compartment 35 at a distance from the outlet vent 43 in order to avoid recirculation of air. The air circulation in the system may be achieved by a system cooling unit (not shown) providing a flow of air from the air inlet compartment 35 to the air outlet compartment 37, through the at least one interchangeable modular component 26. Alternatively, the at least one interchangeable modular component 26 is provided with a local cooling unit (not shown) providing a flow of air from the air inlet compartment 35 to the air outlet compartment 37. As is indicated, the complementary component positions 39 are arranged to provide a relatively air flow tight fit with respect to the internal non fluidics section 32 of the interchangeable modular components 26, and according to one embodiment, this may be achieved by a sealing arrangement. In FIG. 5b, there is shown a sealing member 45 for sealing the interchangeable modular components 26 with respect to the liquid handling panel 22, as discussed above. Other sealing member arrangements may be envisaged by a person skilled in the art. According to one embodiment, fluids are strictly restricted to the fluidics section 30 of the interchangeable modular component 26, but in alternative embodiments, only fluid connections are restricted to the fluidics section 30 allowing fluid to "cross" the fluid handling panel inside the non-fluidics section 30 of the interchangeable modular component 26.

In FIG. 5b there is further shown a master control unit 40 and buss connectors 42 for connecting the interchangeable modular components 26 to the master control unit 40. According to one embodiment, the component positions including the buss connectors 42 and the interchangeable modular components 26 are of plug and play configuration with respect to each other.

FIG. 6 is a schematic illustration of an embodiment of a housing 20 with a modular liquid handling panel 22 with the modular components of the liquid chromatography system removed. In the disclosed embodiment, also the layout of the liquid handling panel 22 is configurable by means of two interchangeable panel sections 34 which may be selected in accordance with the desired layout of the system. In FIG. 6 two different layouts of the interchangeable panel sections are disclosed, but the layout may include any suitable configuration.

FIGS. 7a and 7b are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with the modular components of the liquid chromatography system removed. In the disclosed embodiment, the modular housing is comprised of a main housing 36 that comprises the master control unit including power supply and climate control for the whole housing, two expansion housing modules 38 and a side member 40. This approach provides very flexible expansion possibilities for the chromatography sys-

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tem, while preserving the benefits of a single master control unit including power supply and climate control.

FIG. 8 is a schematic illustration of an embodiment of the system architecture of one embodiment of a modular liquid chromatography system according to the present invention. As mentioned above, the chromatography system may comprise a master control unit 40 arranged to communicate with all modular components e.g. 1-26, over a system bus 42 such as a CAN-bus or the like. In one embodiment, each modular component is provided with a dedicated CPU unit allowing the component to independently perform operations in response to instructions over the BUS 42. In order to minimize the number of connectors to be attached to each modular component, the bus 42 further comprises power feed for the modular components. The Bus 42 may be connected to any suitable number of modular components arranged in the housing 20, but also to one or more modular components 44 outside of the housing 20 or the like. As is mentioned briefly above, the master control unit may further be arranged to control the climate in the housing. In addition to the disclosed modular components, other components of the chromatography system, e.g. a fraction collector or the like, may be arranged in the housing and the controlled climate therein.

According to one embodiment, different component modules are automatically identified by the master control unit, whereby they may be moved essentially freely between different positions. Moreover, the master control unit may be arranged to provide said information to Chromatography control software whereby experimental setup and planning may be performed. In one embodiment, the control system may be arranged to provide an optimized layout of the component modules with respect to the present layout of the liquid handling panel and available component modules for a specific experimental setup.

According to one embodiment, the interchangeable panel sections 34 of FIG. 5 and the expansion housing modules 38 of FIGS. 6a and 6b may be provided with means for automatic detection of the same to allow automatic configuration of the system by the master control unit 40. In one embodiment, each interchangeable panel section 34 and expansion housing module 38 comprises a hub (not shown) for connection to the system bus 42 in order to expand the system bus 42 network to the number of component modules in each interchangeable panel section 34 or expansion housing module 38.

FIG. 9 is a schematic illustration of an embodiment of a master control unit of one embodiment of a modular liquid chromatography system according to the present invention. The master control unit 40 comprises a system controller 46 for communicating with internal and external components and control computers (not shown) etc. According to one embodiment, the system controller comprises a suitable CPU 48, a bus controller 52, an external communications controller 50, such as a LAN unit, and a storage device 54. The bus controller 52 is providing communication with the component modules. The master control unit may further comprise a Power supply 56 and a climate controller 58 arranged to keep the internal climate in the housing 20 at a predetermined level as discussed above.

FIG. 10 is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel. Taking into account the complexity of the disclosed interconnection arrangement, the benefit of optimizing the fluid paths in alternative configurations of the system becomes evident. The task of optimizing the fluid paths may e.g. be performed



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to reduce the total length/volume of the fluid paths/tubing arranged to interconnect the different component modules in the system. Alternatively the optimization may be performed to minimize the length/volume of one or more specific fluid paths, such as the sample output path from the column to the fraction collector, in order to minimize dispersion of the fractionized sample.

The invention claimed is:

1. An automated liquid chromatography system comprising a housing unit and at least four modular fluid handling units,

wherein the housing unit

comprises on one external side of the housing unit a plurality of receiving positions, each receiving position adapted to receive the modular fluid handling units therein such that a fluid handling section thereof is on the external side of the housing unit, the receiving positions being arranged in a two dimensional array,

wherein each modular fluid handling unit

is configured for insertion into the receiving positions of the housing unit,

is readily interchangeable amongst similarly sized and shaped receiving positions of the housing unit, such that positioning of the modular fluid handling unit with respect to other modular fluid handling units permits a fluid flow path to be readily modified, wherein the fluid flow path is formed by fluidic connections between the modular fluid handling units, and

includes a CPU for independently performing fluid control operations in response to instructions over a system BUS.

2. The automatic liquid chromatography system of claim 1, wherein the modular fluid handling units are each connected to the system BUS.

3. The automatic liquid chromatography system of claim 1, wherein the modular fluid handling units include a double piston pump, a sample pump, an inlet valve for selecting inlet fluid to a respective pump, an injection valve for injecting a sample onto a column connected to the flow fluid path of the liquid chromatography system, a column valve for connecting one of a plurality of columns to the flow fluid path, a UV-monitor, a mixer, a pH valve with an integrated flow cell for in-line monitoring of pH levels, a quaternary valve for automatic buffer preparation for formation of quaternary gradients, or any combination thereof.

4. The automatic liquid chromatography system of claim 1, further comprising an expansion housing unit that includes a plurality of receiving positions, each receiving position being adapted to receive the modular fluid handling units.

5. The automatic liquid chromatography system of claim 1, wherein the CPU automatically configures the modular fluid handling unit within the liquid chromatography system upon insertion into the receiving positions of the housing unit.

6. An automated liquid chromatography system comprising a housing unit and at least four freely arrangeable modular fluid handling units that control fluid flow through at least one chromatography column when fluidically interconnected to form a fluid flow path, wherein:

the housing unit is adapted to receive the modular fluid handling units;

the modular fluid handling units are adapted to fit into receiving positions of the housing unit, and each modular fluid handling unit includes a CPU for performing

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fluid control operations independently irrespective of the location within the housing unit; and  
a master control unit arranged to communicate through a system BUS to each fluid handling unit.

7. The automatic liquid chromatography system of claim 6, wherein said housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are freely arrangeable modular fluid handling units.

8. The automatic liquid chromatography system of claim 1, wherein the housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are arranged as modular fluid handling units.

9. The automatic liquid chromatography system of claim 8, wherein the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, and an outlet valve.

10. The automatic liquid chromatography system of claim 1, wherein the fluid handling section of the modular fluid handling unit is sealed from an internal side of the housing unit when received in a receiving position of the housing unit.

11. The automatic liquid chromatography system of claim 1, wherein the modular fluid handling units are of the same size.

12. The automatic liquid chromatography system of claim 1, wherein the modular fluid handling units are of two or more sizes.

13. The automatic liquid chromatography system of claim 1, wherein the automatic liquid chromatography system further comprises a pH electrode that is external to the housing unit, and

wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit.

14. The automatic liquid chromatography system of claim 13, wherein the pH valve includes an integrated flow cell for in-line monitoring of pH levels.

15. The automatic liquid chromatography system of claim 1, wherein the modular fluid handling units include two double piston pumps, one injection valve for injecting sample onto a column connecting a flow path of the liquid chromatography system, a UV monitor, and a mixer.

16. The automatic liquid chromatography system of claim of claim 15, wherein the automatic liquid chromatography system further includes a column valve comprising pressure sensors integrated into inlet an outlet ports of the column valve for measuring the actual pressure over the connected column.

17. The automatic liquid chromatography system of claim of claim 15, wherein the automatic liquid chromatography system further includes a sample inlet valve.

18. The automatic liquid chromatography system of claim of claim 15, wherein the automatic liquid chromatography system further includes a conductivity monitor.

19. The automatic liquid chromatography system of claim 7, wherein the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, and an outlet valve.

20. The automatic liquid chromatography system of claim 6, wherein the modular fluid handling unit includes one or more fluid connectors for connecting the modular fluid handling unit to the fluid path and wherein all fluid connec-

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tors are on an external side of the housing unit when the modular fluid handling unit is fitted into a receiving position of the housing unit.

21. The automatic liquid chromatography system of claim 20, wherein the fluid handling section of the modular fluid handling unit is sealed from an internal side of the housing unit when fitted in a receiving position of the housing unit.

22. The automatic liquid chromatography system of claim 6, wherein the modular fluid handling units are of the same size.

23. The automatic liquid chromatography system of claim 6, wherein the modular fluid handling units are of two or more sizes.

24. The automatic liquid chromatography system of claim 6, wherein the automatic liquid chromatography system further comprises a pH electrode that is external to the housing unit, and

wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit.

25. The automatic liquid chromatography system of claim 24, wherein the pH valve includes an integrated flow cell for in-line monitoring of pH levels.

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26. The automatic liquid chromatography system of claim 6, wherein the modular fluid handling units include two double piston pumps, one injection valve for injecting a sample onto a column connecting a flow path of the liquid chromatography system, a UV monitor, and a mixer.

27. The automatic liquid chromatography system of claim of claim 26, wherein the automatic liquid chromatography system further includes a column valve comprising pressure sensors integrated into inlet and outlet ports of the column valve for measuring the actual pressure over the connected column.

28. The automatic liquid chromatography system of claim of claim 26, wherein the automatic liquid chromatography system further includes a sample inlet valve.

29. The automatic liquid chromatography system of claim 26, wherein the automatic liquid chromatography system further includes a conductivity monitor.

30. The automatic liquid chromatography system of claim 6, wherein the receiving positions of the housing are arranged in a two dimensional array.

\* \* \* \* \*

# EXHIBIT 33



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(12) **United States Patent**  
**Blomberg et al.**

(10) **Patent No.:** **US 9,709,590 B2**

(45) **Date of Patent:** **Jul. 18, 2017**

(54) **AUTOMATED FLUID HANDLING SYSTEM**

2201/54 (2013.01); G01N 2030/027 (2013.01);

G01N 2030/8804 (2013.01); G01N 2030/8881

(2013.01);

(71) Applicant: **GE HEALTHCARE BIO-SCIENCES**  
**AB**, Uppsala (SE)

(Continued)

(72) Inventors: **Johan Blomberg**, Uppsala (SE); **Mats Lundkvist**, Uppsala (SE)

(58) **Field of Classification Search**

None

See application file for complete search history.

(73) Assignee: **GE HEALTHCARE BIO-SCIENCES**  
**AB**, Uppsala (SE)

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(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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Primary Examiner — Richard Gurtowski

(30) **Foreign Application Priority Data**

(74) Attorney, Agent, or Firm — Arent Fox LLP

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(57) **ABSTRACT**

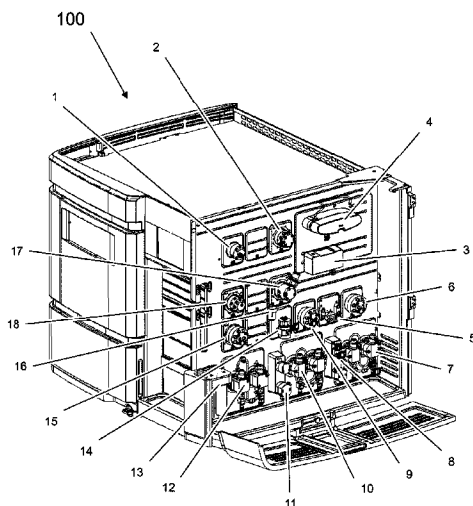
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CPC ..... **G01N 35/1097** (2013.01); **B01D 15/10** (2013.01); **B01D 29/60** (2013.01); **G01N 30/24** (2013.01); **G01N 30/38** (2013.01); **G01N 30/88** (2013.01); **B01D 15/08** (2013.01); **B01D 17/12** (2013.01); **B01D**

Automated fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components with an external fluidics section and an internal non fluidics section, and wherein the housing comprises a liquid handling panel with two or more of component positions for receiving said interchangeable modular components such that the external fluidics section is separated from the non fluidics section by the liquid handling panel.

**20 Claims, 10 Drawing Sheets**



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## Related U.S. Application Data

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**B01D 17/12** (2006.01)  
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**G01N 30/02** (2006.01)

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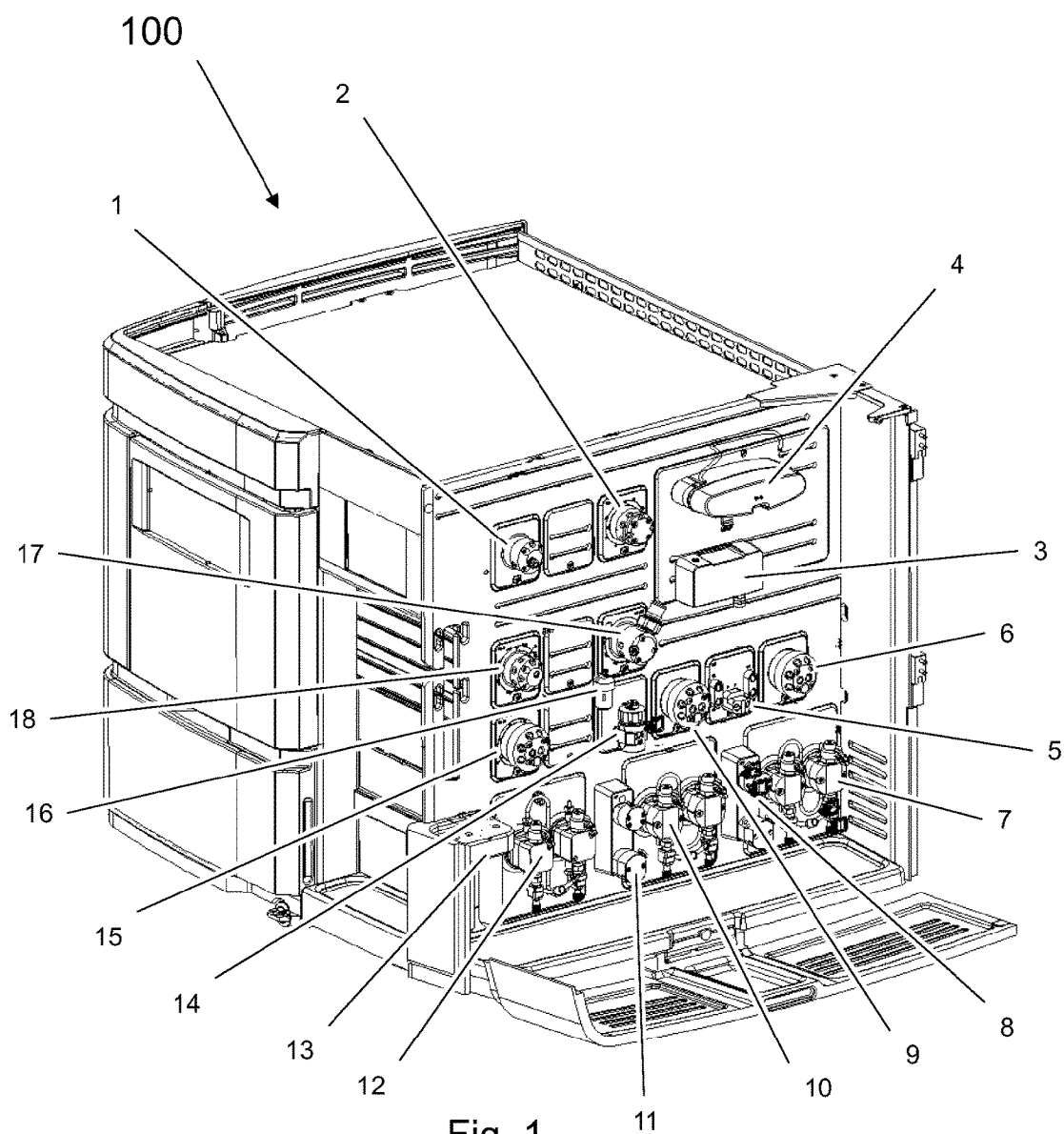


Fig. 1

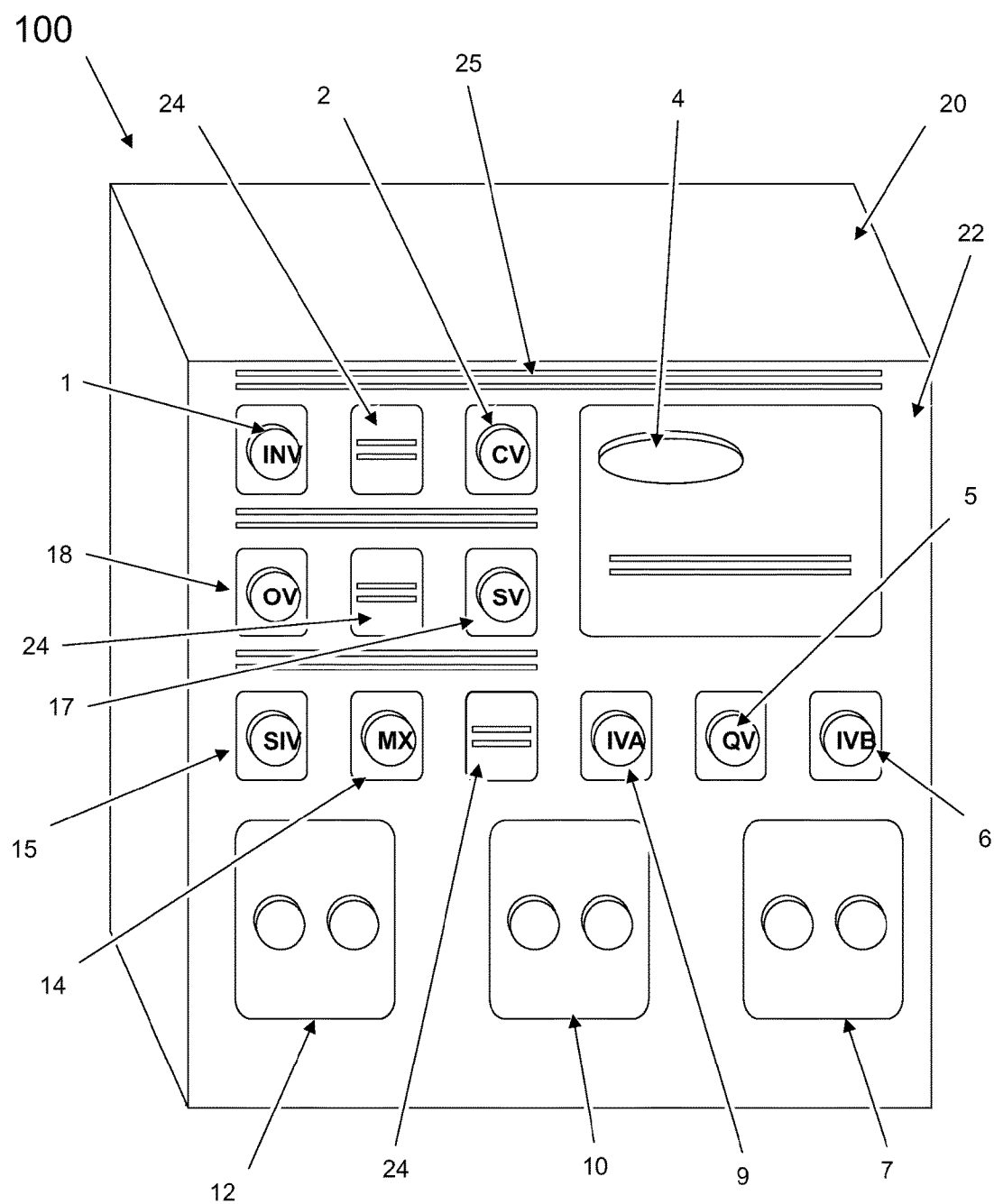


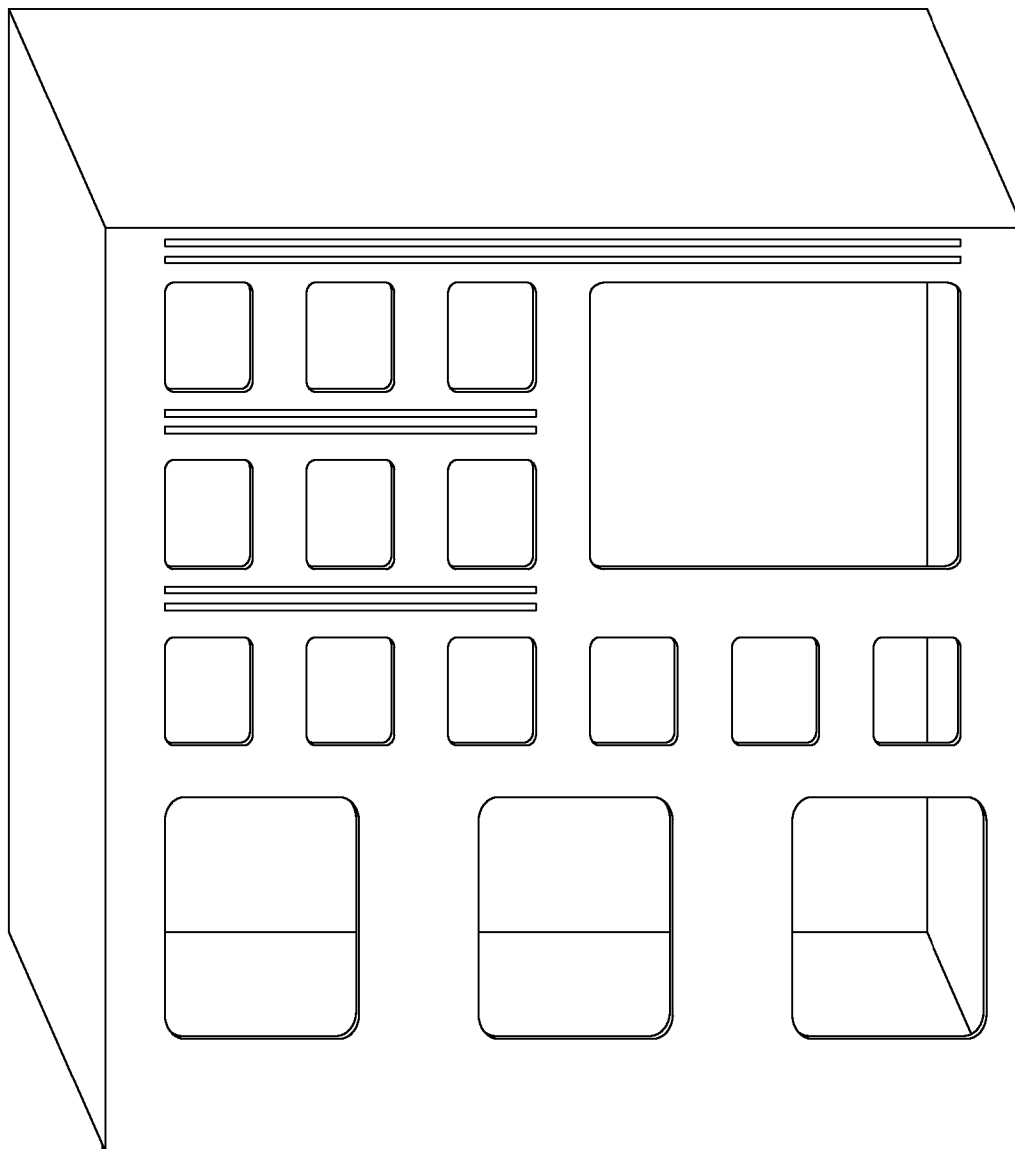
Fig. 2

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**Fig. 3**

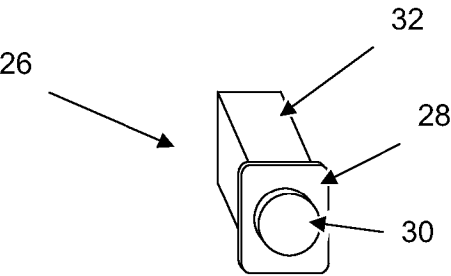


Fig. 4a

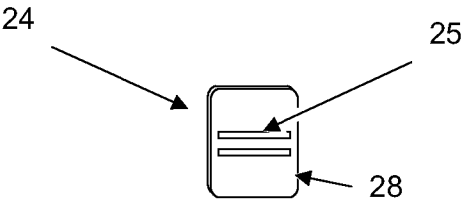


Fig. 4b

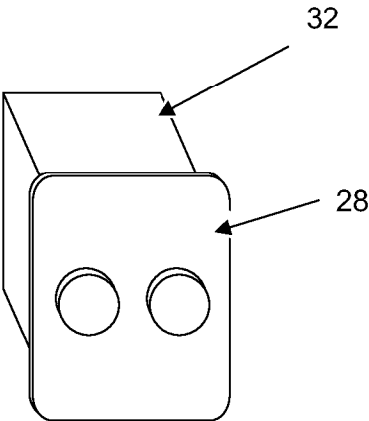


Fig. 4c

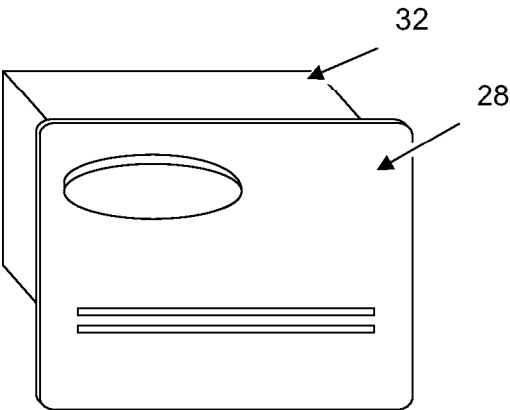


Fig. 4d

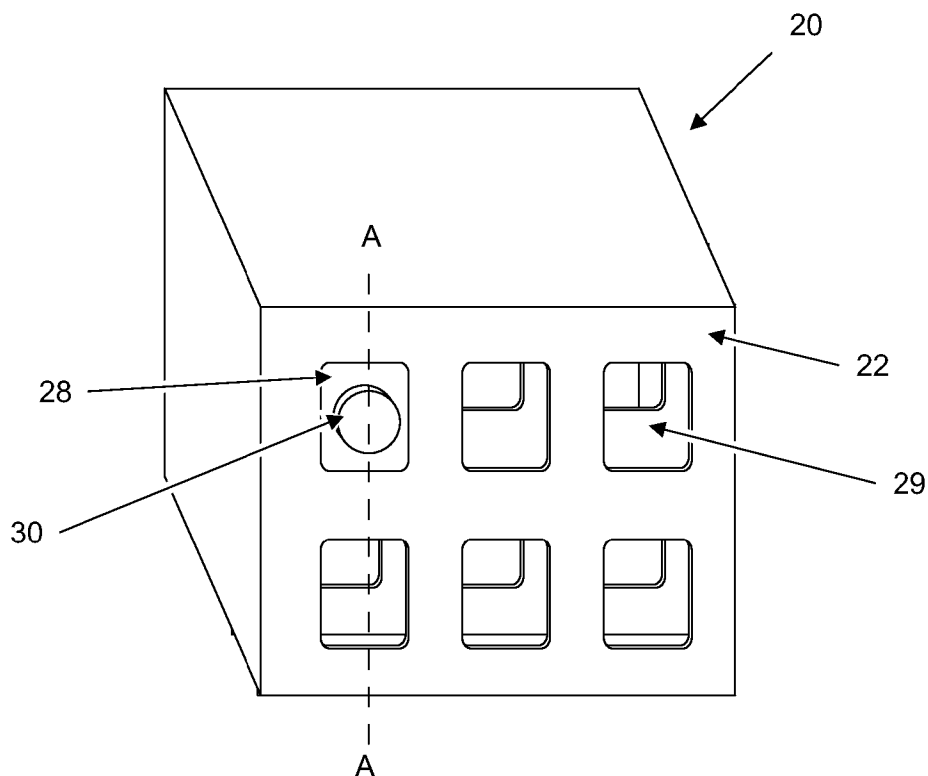


Fig. 5a

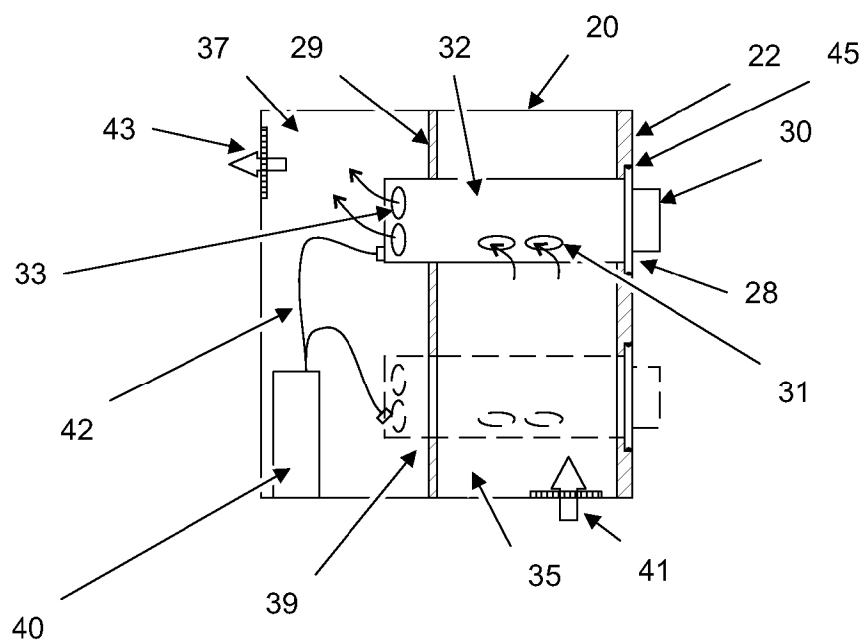


Fig. 5b

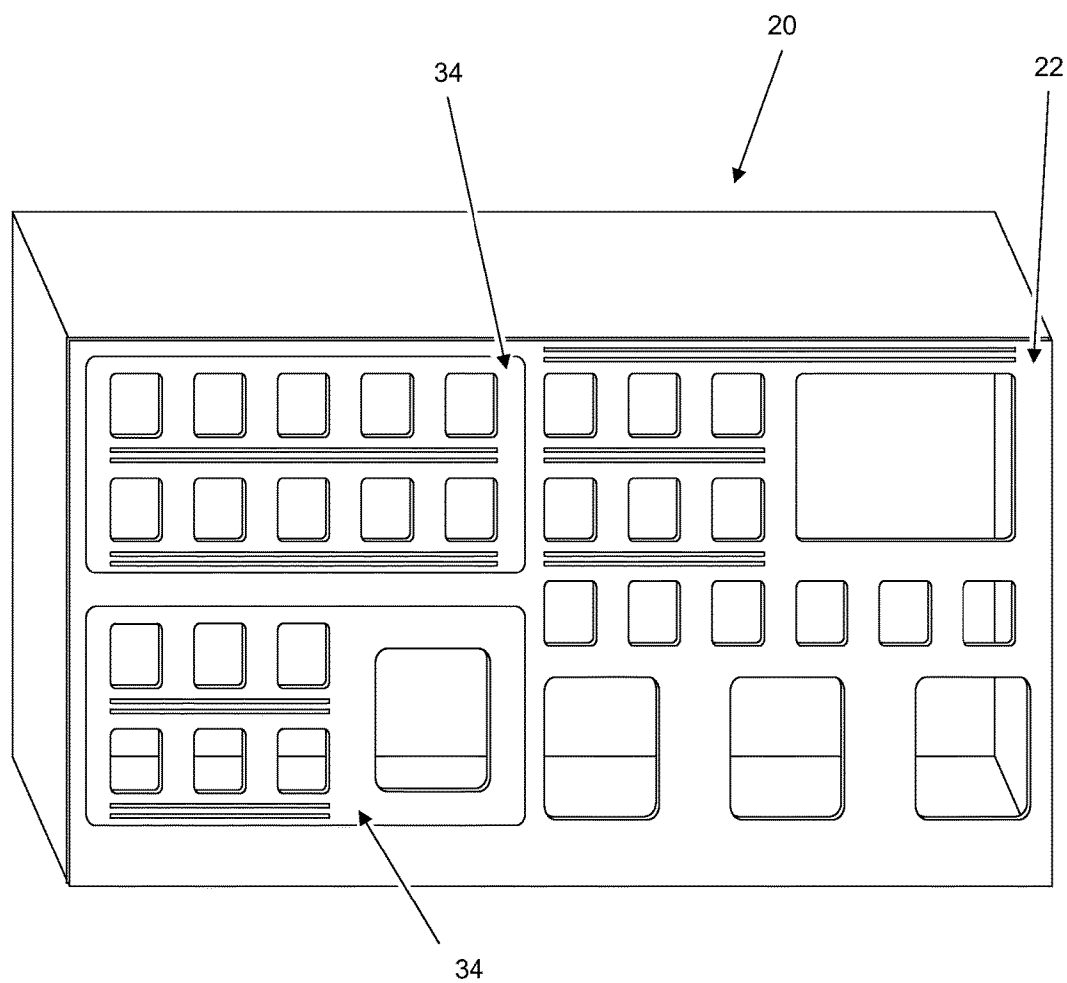


Fig. 6



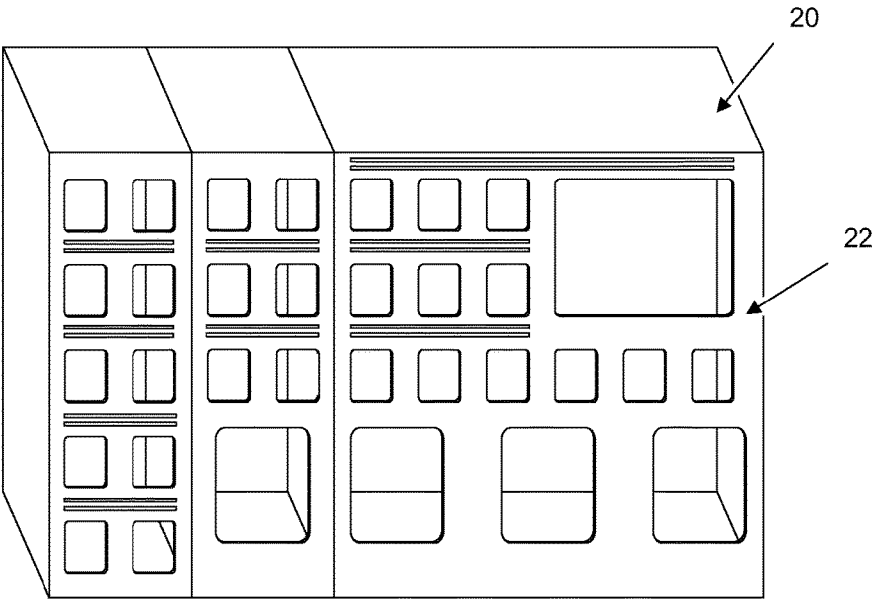


Fig. 7a

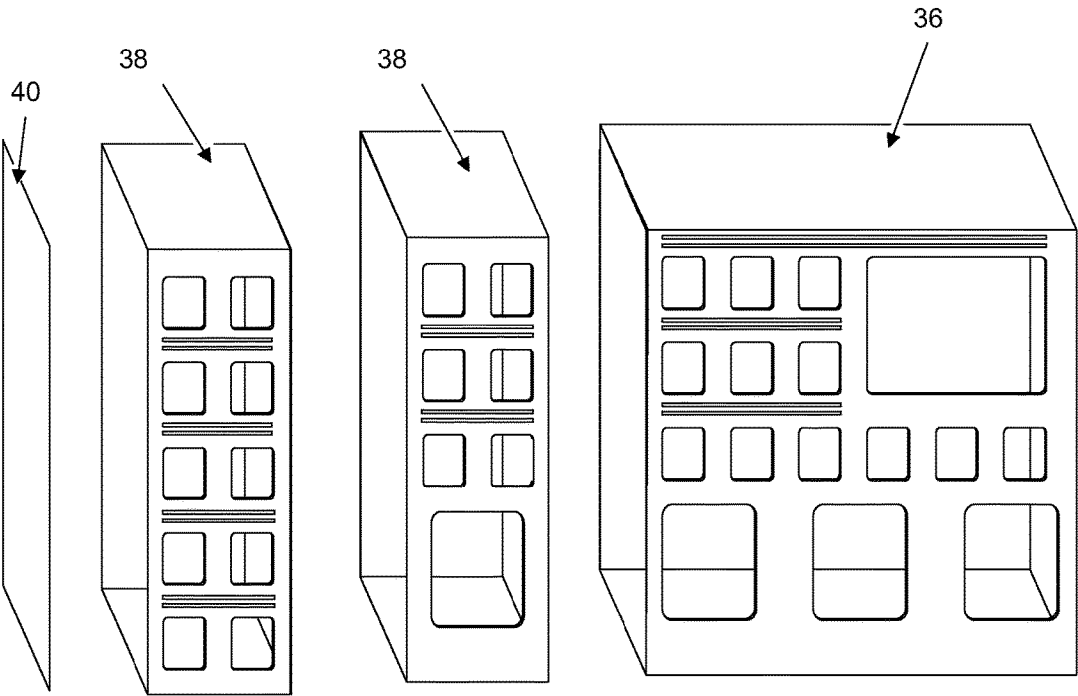
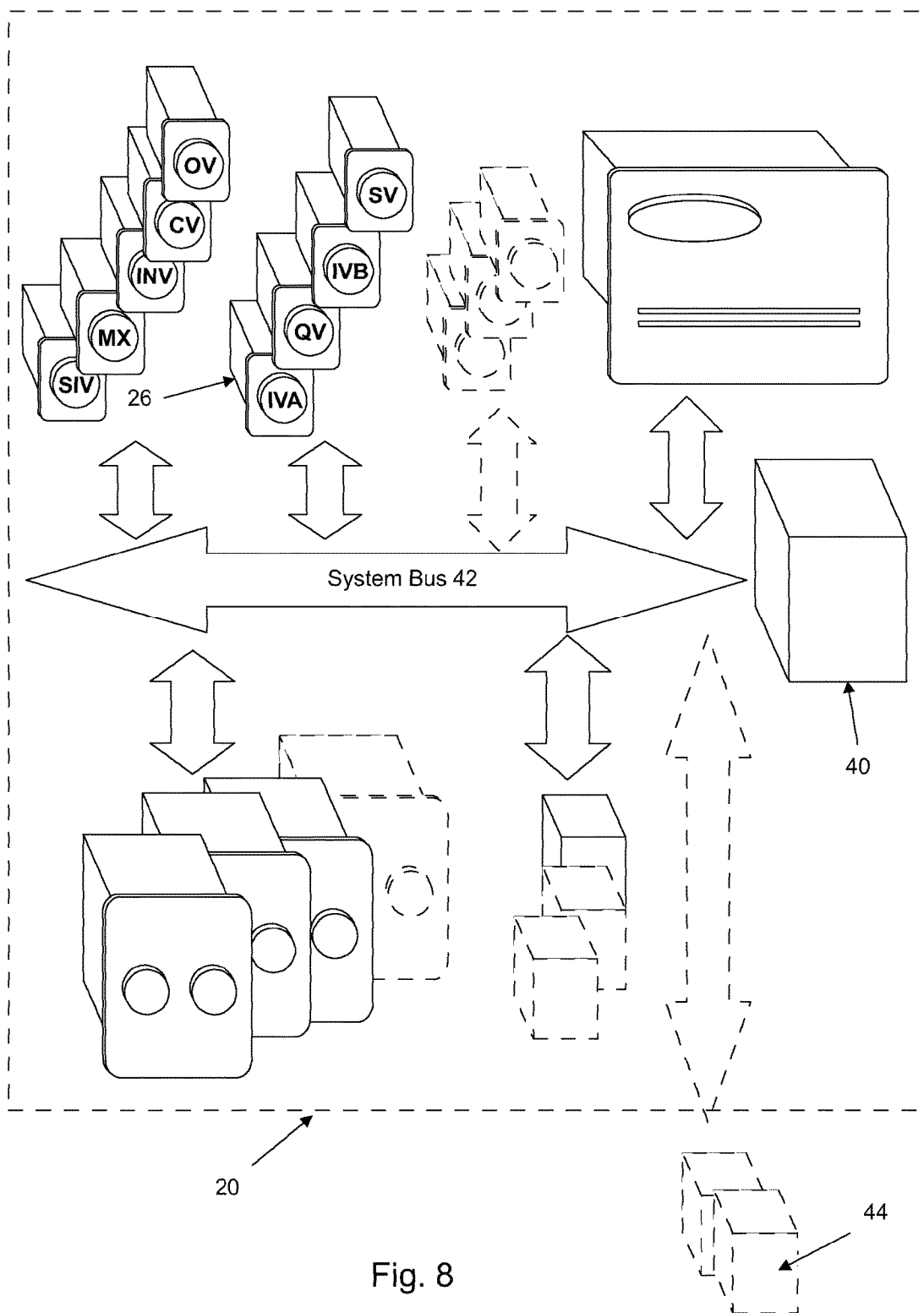


Fig. 7b



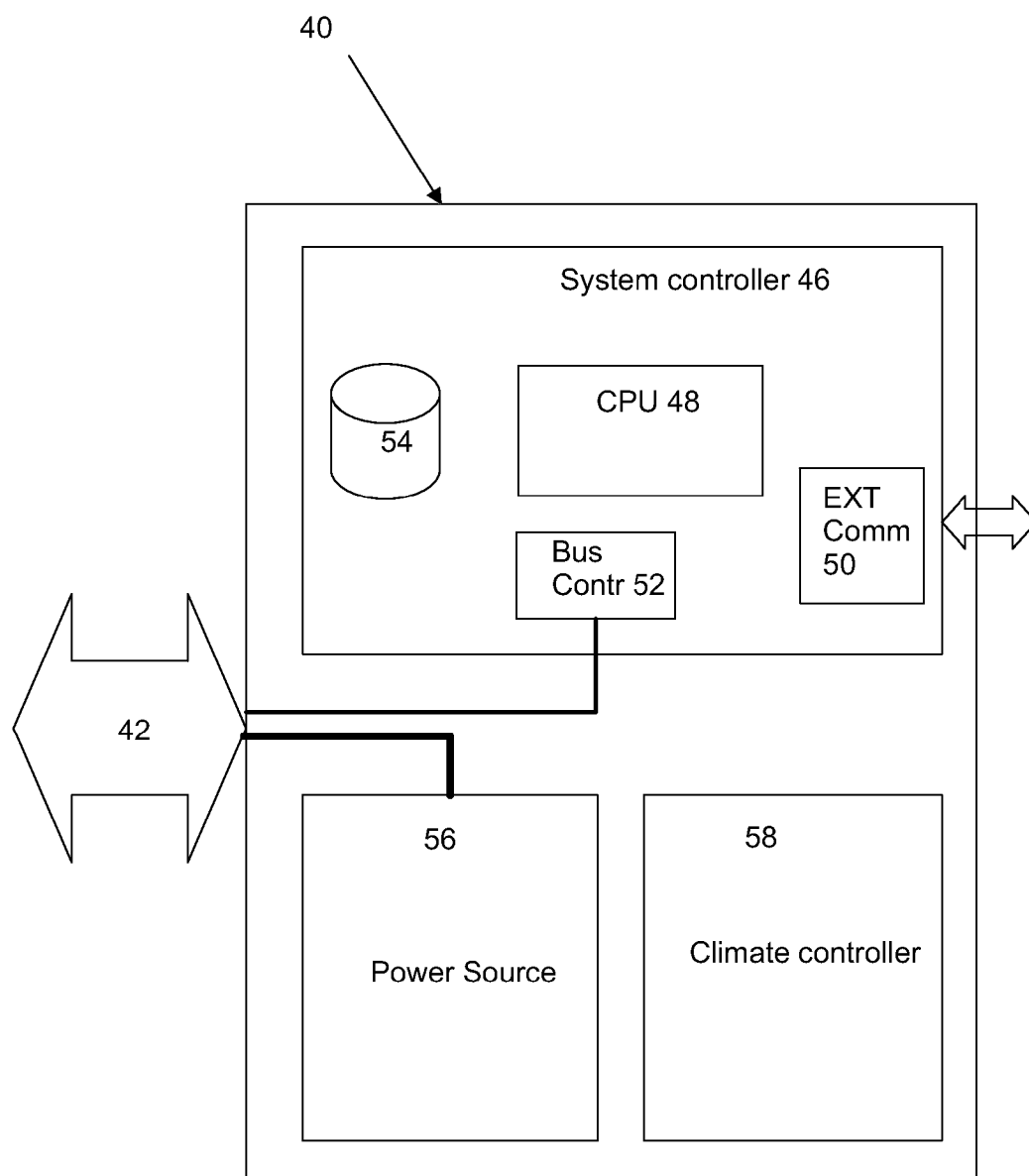


Fig. 9

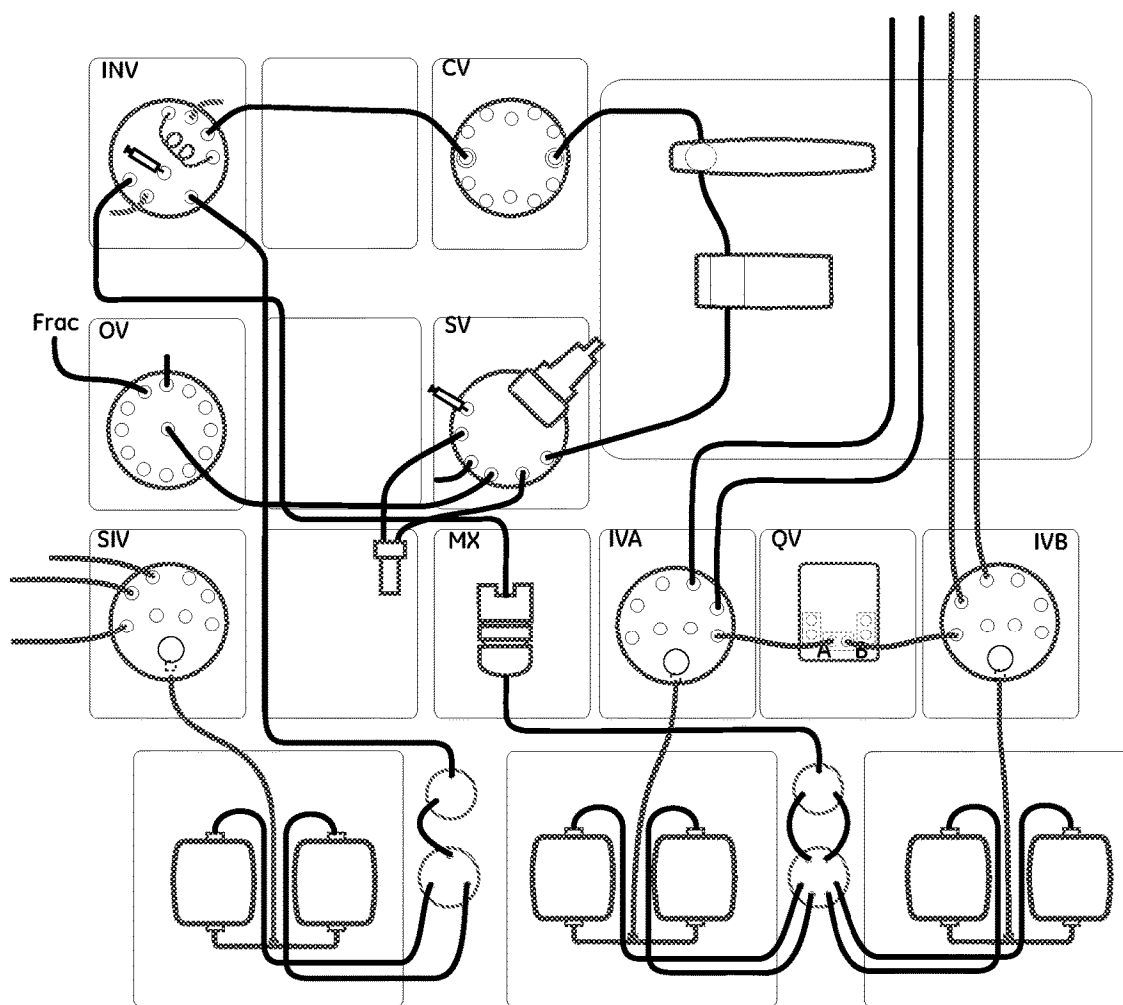


Fig. 10

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**AUTOMATED FLUID HANDLING SYSTEM****CROSS REFERENCE TO RELATED APPLICATION**

This application is a Divisional of U.S. patent application Ser. No. 15/165,876 filed May 26, 2016 which is a Continuation of U.S. patent application Ser. No. 14/463,039 filed Aug. 19, 2014 which is a Continuation of U.S. patent application Ser. No. 13/376,929 filed Dec. 8, 2011 which is a 35 U.S.C. 371 National Phase of International Patent Application No. PCT/SE2010/050624 filed Jun. 4, 2010 which claims priority to Swedish Patent Application No. 0950431-7 filed Jun. 9, 2009, the disclosure of these prior applications are hereby incorporated in their entirety by reference

**BACKGROUND OF THE INVENTION**

The present invention relates to the art of fluid handling system systems, and in particular to an automated fluid handling system that is highly flexible and configurable. The fluid handling system may e.g. be a liquid chromatography system, a filtration system, a chemical synthesis system or the like.

There is a large range of fluid handling systems e.g. in laboratories. Such systems comprise a number of fluid handling units, e.g. one or more pumps, valves, mixers, sensor units etc of different types. Said fluid handling units are interconnected by fluid conduits in the form of, rigid or flexible tubes or the like. Even though some systems may be designed for a specific type of application with a specific flow path, there often exists a need for flexibility and ability to alter or optimize the fluid flow path of the system. Moreover, upgrading is often restricted to specific kits provided by the manufacturer, and upgrade kits often is supplied as external add-on equipment to be arranged besides the original system, thus enlarging the foot print of the system and that need to be connected to the system both fluidically and electrically (i.e. to a system control bus or the like). Moreover, replacement of defect fluid handling units is a time consuming and delicate task.

One type of liquid handling system is liquid chromatography systems which is a standard method in laboratories, and there are a broad range of liquid chromatography systems available on the market. Common to most of the present systems is the lack of flexibility in adapting the instrument to a variety of different applications.

**SUMMARY OF THE INVENTION**

The object of the invention is to provide a new fluid handling system, which system overcomes one or more drawbacks of the prior art. This is achieved by the fluid handling system as defined in the independent claims.

One advantage with such a fluid handling systems is that the system may easily be upgraded without need for add-on equipment, and that the flow path may be easily optimized for new experimental setups.

Embodiments of the invention are defined in the dependent claims.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The invention will be described in detail below with reference to the drawings, in which

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FIG. 1 shows one embodiment of a fluid handling system in the form of a liquid chromatography system, according to the present invention.

FIG. 2 is a schematic illustration of a housing with a liquid handling panel of the fluid handling system of FIG. 1.

FIG. 3 is a schematic illustration of the housing with the liquid handling panel of FIG. 2 with the modular components of the fluid handling system removed.

FIGS. 4a to 4d are schematic illustrations of examples of component modules of the fluid handling system removed.

FIGS. 5a and 5b show a schematic embodiment of an automated fluid handling system.

FIG. 6 is a schematic illustration of an embodiment of a housing with a modular liquid handling panel with the modular components of the fluid handling system removed.

FIGS. 7a and 7b are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with the modular components of the fluid handling system removed.

FIG. 8 is a schematic illustration of an embodiment of the system architecture of one embodiment of a fluid handling system according to the present invention.

FIG. 9 is a schematic illustration of an embodiment of a master control unit of one embodiment of a fluid handling system according to the present invention.

FIG. 10 is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel for the liquid chromatography system of FIG. 1.

**DETAILED DESCRIPTION OF THE INVENTION**

According to one embodiment, there is provided an automated fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components with an external fluidics section and an internal non fluidics section, and wherein the housing comprises a liquid handling panel with two or more of component positions for receiving said interchangeable modular components such that the external fluidics section is separated from the non fluidics section by the liquid handling panel.

According to another embodiment, there is provided a fluid handling system in the form of a liquid chromatography system comprising a housing, two or more high pressure pumps, at least one sensor unit and a plurality of fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components and the housing comprises a liquid handling panel with a plurality of component positions for receiving said modular components.

FIG. 1 shows one embodiment of an automated fluid handling system modular in the form of a liquid chromatography system, with a plurality of interchangeable modular components arranged in a liquid handling panel wherein the reference numbers denotes:

1. Injection valve
2. Column valve with integrated pressure sensors
3. Conductivity monitor
4. UV monitor
5. Quaternary valve
6. Inlet valve B with integrated air sensor
7. System pump
8. Pressure monitor, system pump
9. Inlet valve A with integrated air sensor
10. System pump

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11. Pressure monitor, sample pump
12. Sample pump
13. Rinsing system
14. Mixer with online filter
15. Sample inlet valve with integrated air sensor
16. Flow restrictor
17. pH valve
18. Outlet valve

The disclosed embodiment is supplied with three high precision pumps 7, 10, 12. There are two System pumps 7, 10, System pump A 10 and System pump B 7, and one Sample pump 12. The System pumps 7, 10 may be used individually, or in combination to generate isocratic or gradient elution in purification methods. The Sample pump 12 is dedicated for direct loading of sample onto a column, or for filling of sample loops.

#### Function of the Pumps:

Each pump module consists of two pump heads (not shown). The individual heads are identical but actuated in opposite phase to each other by individual stepper motors, controlled by a microprocessor. The two pistons and pump heads work alternately to give a continuous, low pulsation, liquid delivery. The flow rate of the two System pumps may be varied between about 0.001 ml/min and 25.000 ml/min and the maximum operating pressure is about 20 MPa. The flow rate of the Sample pump may e.g. be varied between 0.01 and 25 ml/min and according to one embodiment the maximum operating pressure is 10 MPa.

According to one embodiment, the plurality of fluid control valves of at least two different configurations are valves of rotary type. Such a motorized rotary valve may consist of a Valve head with a number of defined bores with channels to the inlet and outlet ports of the valve. The Rotary disc, mounted on the motor, has a number of defined channels. The pattern of channels of the Rotary disc together with the pattern and location of the ports of the Valve head, define the flow path and function of each type of valve. When the Rotary disc turns, the flow path in the valve changes.

One embodiment of fluid control valves are Inlet valves A and B (9, 6 respectively) that are used to select which buffers or samples to use in a run, and Sample inlet valve 15 that is located before Sample pump 12. Inlet valve A 9 is located before System pump A 10, Inlet valve B 6 is located before System pump B 10, and Sample inlet valve 15 is located before Sample pump 12. Inlet valve A and Inlet valve B are connected to another embodiment of a fluid control valve in the form of a Quaternary valve 5. The Quaternary valve is used for automatic buffer preparation, and for formation of quaternary gradients. The number of inlets can be increased by installing component modules with extra inlet valves. Inlet valve A and Inlet valve B enable automatic changing between different buffers and wash solutions, and can be used to generate gradients by mixing buffer A and buffer B. The air sensors integrated in Inlet valve A and Inlet valve B can be used to prevent introduction of air into the pumps and columns.

The Quaternary valve is used for automatic mixing of four different solutions. The Quaternary valve opens one inlet port at a time, and the different solutions are mixed in a Mixer 14 to form the desired buffer. The opening time in the switching valve is controlled by the system. The volume for each inlet port opening increases stepwise when the flow increases. To obtain a homogeneous buffer composition, one has to make sure to use a mixer chamber volume suitable for the flow rate of the method.

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The Quaternary valve can be used to create a gradient using four different solutions simultaneously in any combination. The percentage of each solution is controlled by instructions in the method. It is possible to form gradients that changes the percentage of two, three or four solutions linearly over time. This is useful when advanced methods are developed.

The Sample inlet valve 15 enables automatic loading of different samples when using the Sample pump 12 to inject sample directly onto the column or to fill a sample loop. The Sample inlet valve has an inlet dedicated for buffer. This Buffer inlet is used in methods to fill the Sample pump with solution before sample is introduced. The Buffer inlet is also used to wash the Sample pump with buffer between runs. The air sensor integrated in the Sample inlet valve is e.g. used when sample is applied from a vessel onto a column by selecting Inject all sample using air sensor in the Sample application phase of a method. This function uses the Buffer inlet is used to finalize sample injection and to remove air from the Sample pump.

Still another embodiment of fluid control valve may be an Injection valve 1, which is used to direct sample onto the column. The valve enables usage of a number of different sample application techniques. A sample loop can be connected to the Injection valve and filled either automatically using the Sample pump or manually using a syringe. The sample can also be injected directly onto the column using the Sample pump.

Still another embodiment of fluid control valve may be a Column valve 2 that is used for connection of columns to the system, and to direct the flow onto the column. Up to five columns can be connected to the disclosed embodiment of said valve simultaneously. The valve also has a built-in bypass capillary that enables bypassing of connected columns.

The number of column positions can be increased by installing an extra Column valve. Both top and bottom of each column shall be connected to the Column valve. The top of the column shall be connected to one of the A ports (e.g., 1A), and the bottom of the column shall be connected to the corresponding B port (e.g., 1B). The flow direction can be set either from the top of the column to the bottom of the column, Down flow, or from the bottom of the column to the top of the column, Up flow. In the default flow path of the Column valve the columns are bypassed. Pressure monitors that measures the actual pressure over the column are integrated into the inlet and outlet ports of the Column valve.

Still another embodiment of fluid control valve may be a pH valve 17 that has an integrated flow cell where a pH electrode can be installed. This enables in-line monitoring of pH during the run. A flow restrictor is connected to the pH valve and can be included in the flow path to generate a backpressure high enough to prevent formation of air bubbles in the UV flow cell. The pH valve is used to direct the flow to the pH electrode and to the flow restrictor, or to bypass one or both.

Still another embodiment of fluid control valve may be an Outlet valve 18 that is used to direct the flow to a Fraction collector (not shown), to any of e.g. 10 outlet ports, or to waste. The number of outlets can be increased by installing an extra Outlet valve.

A Mixer 14 may e.g. be located after System pump A and System pump B and before the Injection valve. The purpose of the Mixer is to make sure that the buffers from the System

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pumps are mixed to give a homogenous buffer composition. The Mixer has a built-in filter that prevents impurities from entering the flow path.

To fulfill a desired purpose, with the disclosed liquid chromatography system it is possible to adapt and extend the flow path in a simple and a flexible way. Up to three extra fluid control valves or the like can be installed using the free valve positions. Dummy modules are installed in these positions at delivery. To obtain an optional flow path, it is also possible to move the standard fluid control valves to other positions. There are also two types of extra air sensors available which can be installed before Sample inlet valve or after Injection valve.

In the configuration disclosed in FIG. 1, 7 inlets are available for each inlet valve. To increase the number of inlets, an extra inlet valve can be installed which increases the number of inlets to 14 for one of the valves. This optional configuration can be convenient for example when a larger number of samples will be used. There is also a general type of inlet valve, Valve X, which can be used to increase the number of inlets to for example the Quaternary valve.

In the configuration disclosed in FIG. 1 with one column valve, 5 column positions are available. To increase the number of column positions to 10, an additional column valve can be installed in the instrument. An application can be to evaluate a number of different columns in method optimization.

In the configuration disclosed in FIG. 1 with one outlet valve, 10 outlet positions are available. To increase the number of outlets, one or two extra outlet valves can be connected, adding up to a total of 21 or 32 outlet positions. This optional configuration is convenient when collecting a number of large fractions outside the fraction collector.

Optional modules are easy to install in the disclosed modular liquid chromatography system. The dummy module is removed with a hexagon wrench and a bus cable is disconnected. The bus cable is connected to the optional fluid control valve or the like which is assembled in the instrument. The module is then added to the System properties in the control software. The available optional modules may e.g. be pre-configured to give the desired function. However, the function of a valve may e.g. be changed by changing the Node ID.

FIG. 2 is a schematic illustration of a housing 20 with a liquid handling panel 22 of the fluid handling system in the form of a modular liquid chromatography system 100 of FIG. 1. In FIG. 2 some components have been removed for clarity reasons. In the disclosed configuration, as disclosed in detail above, the modular liquid chromatography system 100 comprises a plurality of fluid control valves in the form of: Injection valve 1, Column valve 2, Quaternary valve 5, Inlet valve B 6, Inlet valve A 9, Sample inlet valve 15, pH valve 17, and Outlet valve 18. The chromatography system 100 further comprises UV monitor 4, System pump B 7, System pump A 10, Sample pump 12, Mixer 14, and three Dummy modules 24. According to one embodiment, all liquid handling components and sensors arranged at the liquid handling panel 22 are designed to be readily interchangeable. The interchangeability provides improved service and upgrade possibilities and also a possibility to customize the positions of the respective liquid handling components, such as the fluid control valves, e.g. in order to optimize the fluid path for a specific experimental setup. As is illustrated in FIG. 2, there are three large component positions e.g. for pump modules, one UV-sensor position and 9 standard component positions, e.g. for fluid control valves or the like. The component positions are given a

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standardized size and shape to provide simple interchangeability. According to one embodiment, each modular component is retained in a mating component position by a single screw, and it is connected to the master control unit by a single bus cable providing both communication and system power to each component. FIG. 3 is a schematic illustration of the housing with the liquid handling panel of FIG. 2 with the modular components of the liquid chromatography system removed.

FIGS. 4a to 4d are schematic illustrations of examples of fluid handling units in the form of modular component of the fluid handling system removed. FIG. 4a shows a standard interchangeable modular component 26, e.g. a fluid control valve or the like. The standard component module 26 comprises a panel member 28, an external fluidics section 30 and an internal non-fluidics section 32. According to one embodiment, the panel member 28 essentially separates the fluidics in the external fluidics section 30 from electronics and control means in the internal non-fluidics section 32.

FIG. 4b shows a Dummy module 24, which is intended to be placed in non used standard component positions. In the disclosed embodiment, the Dummy modules are provided with mounting grooves for attachment of accessories to the system. In the disclosed embodiment the dummy module is shown as a panel member 28 without any internal section. FIGS. 4c and 4d shows a pump module and an UV-module, respectively, each having an external fluidics section 30 and an internal non-fluidics section 32.

As is disclosed in FIGS. 4a to 4d, the interchangeable modular components 26 comprises a panel member arranged to separate the fluidics section from the non fluidics section and for attachment to a component position in the liquid handling panel. Said panel attachment member may be arranged so that all fluid connections of said modular component are arranged on a wet side of the panel attachment member separating them from electrical components that are arranged on a dry side thereof, hence providing a high degree of liquid resistance at the external part of the fluid handling panel, and so that the liquid resistance requirements for the internal sections may be somewhat lightened. According to one embodiment, the interchangeable modular components are sealed against the liquid handling panel by a sealing member. According to another embodiment, not shown, the modular component does not comprise any panel member, but there is provided a suitable sealing arrangement between the component position openings of the liquid handling panel and the external surface of the interchangeable modular components 26. In the disclosed embodiments, the component position openings of the liquid handling panel and the interchangeable modular components 26 are shown to have an essentially rectangular crosssectional shape, but other shapes may be equally applicable. According to one embodiment, there is provided a general fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components as is schematically disclosed in FIG. 5a. As discussed above such a system may be configured for essentially any type of automated liquid handling operations provided that suitable fluid handling units are provided as interchangeable modular components for the system. According to one embodiment there is provided an automated fluid handling system comprising at least one fluid pump, at least one sensor unit and two or more fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components.



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The liquid handling panel **22** of the fluid handling system may e.g. be designed in any suitable manner to allow the modular components to be arranged in an efficient manner.

FIGS. **5a** and **5b** shows a schematic embodiment of an automated fluid handling system wherein the housing **20** comprises an internal climate panel **29** arranged at a distance behind the liquid handling panel **22** defining an air inlet compartment **35** and air outlet compartment **37** in the housing **20**, the climate panel **29** being provided with complementary component positions **39** for receiving the internal non fluidics section **32** of the interchangeable modular components **26**, and wherein the non-fluidics section **32** of at least one interchangeable modular component is provided with one or more air inlet openings **31** located in the air inlet compartment **35** and one or more air outlet openings **33** located in the air outlet compartment **37** when the interchangeable modular component arranged in position in the component position. FIG. **5b** shows the fluid handling system of FIG. **5a** in a schematic cross sectional view. As is indicated by inlet vent **41** and outlet vent **43**, air for cooling interchangeable modular components **26** provided with air inlet and outlet openings **31**, **33** is preferably arranged to enter the air inlet compartment **35** at a distance from the outlet vent **43** in order to avoid recirculation of air. The air circulation in the system may be achieved by a system cooling unit (not shown) providing a flow of air from the air inlet compartment **35** to the air outlet compartment **37**, through the at least one interchangeable modular component **26**. Alternatively, the at least one interchangeable modular component **26** is provided with a local cooling unit (not shown) providing a flow of air from the air inlet compartment **35** to the air outlet compartment **37**. As is indicated, the complementary component positions **39** are arranged to provide a relatively air flow tight fit with respect to the internal non fluidics section **32** of the interchangeable modular components **26**, and according to one embodiment, this may be achieved by a sealing arrangement. In FIG. **5b**, there is shown a sealing member **45** for sealing the interchangeable modular components **26** with respect to the liquid handling panel **22**, as discussed above. Other sealing member arrangements may be envisaged by a person skilled in the art. According to one embodiment, fluids are strictly restricted to the fluidics section **30** of the interchangeable modular component **26**, but in alternative embodiments, only fluid connections are restricted to the fluidics section **30** allowing fluid to "cross" the fluid handling panel inside the non-fluidics section **30** of the interchangeable modular component **26**.

In FIG. **5b** there is further shown a master control unit **40** and buss connectors **42** for connecting the interchangeable modular components **26** to the master control unit **40**. According to one embodiment, the component positions including the buss connectors **42** and the interchangeable modular components **26** are of plug and play configuration with respect to each other.

FIG. **6** is a schematic illustration of an embodiment of a housing **20** with a modular liquid handling panel **22** with the modular components of the liquid chromatography system removed. In the disclosed embodiment, also the layout of the liquid handling panel **22** is configurable by means of two interchangeable panel sections **34** which may be selected in accordance with the desired layout of the system. In FIG. **6** two different layouts of the interchangeable panel sections are disclosed, but the layout may include any suitable configuration.

FIGS. **7a** and **7b** are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with

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the modular components of the liquid chromatography system removed. In the disclosed embodiment, the modular housing is comprised of a main housing **36** that comprises the master control unit including power supply and climate control for the whole housing, two expansion housing modules **38** and a side member **40**. This approach provides very flexible expansion possibilities for the chromatography system, while preserving the benefits of a single master control unit including power supply and climate control.

FIG. **8** is a schematic illustration of an embodiment of the system architecture of one embodiment of a modular liquid chromatography system according to the present invention. As mentioned above, the chromatography system may comprise a master control unit **40** arranged to communicate with all modular components e.g. **1-26**, over a system bus **42** such as a CAN-bus or the like. In one embodiment, each modular component is provided with a dedicated CPU unit allowing the component to independently perform operations in response to instructions over the BUS **42**. In order to minimize the number of connectors to be attached to each modular component, the bus **42** further comprises power feed for the modular components. The Bus **42** may be connected to any suitable number of modular components arranged in the housing **20**, but also to one or more modular components **44** outside of the housing **20** or the like. As is mentioned briefly above, the master control unit may further be arranged to control the climate in the housing. In addition to the disclosed modular components, other components of the chromatography system, e.g. a fraction collector or the like, may be arranged in the housing and the controlled climate therein.

According to one embodiment, different component modules are automatically identified by the master control unit, whereby they may be moved essentially freely between different positions. Moreover, the master control unit may be arranged to provide said information to Chromatography control software whereby experimental setup and planning may be performed. In one embodiment, the control system may be arranged to provide an optimized layout of the component modules with respect to the present layout of the liquid handling panel and available component modules for a specific experimental setup.

According to one embodiment, the interchangeable panel sections **34** of FIG. **5** and the expansion housing modules **38** of FIGS. **6a** and **6b** may be provided with means for automatic detection of the same to allow automatic configuration of the system by the master control unit **40**. In one embodiment, each interchangeable panel section **34** and expansion housing module **38** comprises a hub (not shown) for connection to the system bus **42** in order to expand the system bus **42** network to the number of component modules in each interchangeable panel section **34** or expansion housing module **38**.

FIG. **9** is a schematic illustration of an embodiment of a master control unit of one embodiment of a modular liquid chromatography system according to the present invention. The master control unit **40** comprises a system controller **46** for communicating with internal and external components and control computers (not shown) etc. According to one embodiment, the system controller comprises a suitable CPU **48**, a bus controller **52**, an external communications controller **50**, such as a LAN unit, and a storage device **54**. The bus controller **52** is providing communication with the component modules. The master control unit may further comprise a Power supply **56** and a climate controller **58** arranged to keep the internal climate in the housing **20** at a predetermined level as discussed above.



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FIG. 10 is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel. Taking into account the complexity of the disclosed interconnection arrangement, the benefit of optimizing the fluid paths in alternative configurations of the system becomes evident. The task of optimizing the fluid paths may e.g. be performed to reduce the total length/volume of the fluid paths/tubing arranged to interconnect the different component modules in the system. Alternatively the optimization may be performed to minimize the length/volume of one or more specific fluid paths, such as the sample output path from the column to the fraction collector, in order to minimize dispersion of the fractionized sample.

The invention claimed is:

1. A method of modifying a fluid flow path in an automated liquid chromatography system comprising at least four interchangeable modular components comprising:

interchanging at least two of the interchangeable modular components in a housing unit comprising at least four component receiving positions arranged in a two dimensional array, so as to allow for modification of the liquid chromatography fluid flow path among the at least four interchangeable modular components;

wherein each of the at least four interchangeable modular components comprises a CPU unit for independently performing fluid control operations in response to instructions from a system controller when installed in a component receiving position of the housing unit.

2. The method of claim 1, wherein the interchanging of the at least two interchangeable modular components shortens the fluid flow path for the liquid chromatography.

3. The method of claim 1, wherein the interchanging of the at least two interchangeable modular component shortens the fluid flow path between the interchangeable modular components.

4. The method of claim 1, wherein the interchanging of the interchangeable modular components includes connecting each of the at least four interchangeable modular components to a system BUS.

5. The method of claim 1, wherein the liquid chromatography system further comprises an expansion housing unit that includes a plurality of additional component receiving positions, each component receiving position being capable of receiving the interchangeable modular components, wherein the interchanging of the interchangeable modular components includes arranging at least one of the interchangeable modular components in a component receiving position in the expansion housing unit.

6. The method of claim 1, wherein the interchangeable modular components include a double piston pump, a sample pump, an inlet valve for selecting inlet fluid to a respective pump, injection valve for injecting a sample onto a column connected to the flow path of the liquid chromatography system, a column valve for connecting one of a plurality of columns to the flow path, a UV-monitor, a mixer, a pH valve with an integrated flow cell for in-line monitoring of pH levels, a quaternary valve for automatic buffer preparation for formation of quaternary gradients, or any combination thereof.

7. The method of claim 1, wherein each of the at least four interchangeable modular components are connected to a system BUS by a cable.

8. The method of claim 1, wherein the at least four component receiving positions of the housing unit are of the same size.

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9. The method of claim 1, wherein the at least four component receiving positions of the housing unit are of two or more sizes.

10. The method of claim 1, wherein the interchanging includes

removing an interchangeable modular component from the component receiving position and installing an interchangeable modular component of a different functionality or a dummy module,

installing an extra interchangeable modular component, rearranging one or more of said interchangeable modular components among said at least four modular components,

or any combination thereof.

11. The method of claim 10, wherein said rearranging includes exchanging one interchangeable modular component for another interchangeable modular component.

12. The method of claim 1, wherein the interchanging of the at least two interchangeable modular components provides for upgrading and customizing the liquid chromatography system for various user customizable chromatography set-ups, wherein the placement and interchanging of the interchangeable modular components amongst the at least four component receiving positions and with respect to each of the other interchangeable modular components at the component receiving positions allows for modifying the liquid chromatography fluid flow path.

13. A method for building an automated liquid chromatography system, the method comprising providing a

housing unit comprising a main controller, a power source and at least four component receiving positions arranged in a two dimensional array on one side of the housing, wherein the component receiving positions are of a size and shape that is capable of receiving an interchangeable modular fluid handling unit of a similar size and shape;

placing at least two interchangeable modular fluid handling units components in said component receiving positions; and

the at least two interchangeable modular fluid handling units being readily interchangeable and comprising a CPU that allows independent fluid control operations in response to instructions from the main controller when installed in the component receiving position of the housing unit.

14. The method of claim 13, further comprising adding an expansion housing unit that includes a plurality of component receiving positions, each component receiving position being adapted to receive the at least one interchangeable modular fluid handling unit, and placing at least one additional interchangeable modular fluid handling unit in one of the component receiving positions in the expansion housing.

15. The method of claim 13, wherein the component receiving positions are arranged in a two dimensional array on a panel member that separates an external side from an internal side of the housing.

16. The method of claim 15, wherein the panel member comprises a plurality of component receiving positions of different sizes and shapes.

17. The method of claim 13, wherein the CPU allows for automatic identification by the liquid chromatography system upon placement in a component receiving position of similar size and shape.

18. The method of claim 13, wherein the at least two interchangeable modular fluid handling units are connected to the system by a system BUS.

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**12**

**19.** The method of claim **13**, wherein the at least two component receiving positions of the housing unit are of two or more sizes.

**20.** The method of claim **11**, wherein the exchanging of the another interchangeable modular fluid handling unit is an exchange of a different type.

\* \* \* \* \*

# EXHIBIT 34

US009709591B2

(12) **United States Patent**  
**Blomberg et al.**(10) **Patent No.:** **US 9,709,591 B2**(45) **Date of Patent:** **\*Jul. 18, 2017**(54) **AUTOMATED FLUID HANDLING SYSTEM**(71) Applicant: **GE HEALTHCARE BIO-SCIENCES AB**, Uppsala (SE)(72) Inventors: **Johan Blomberg**, Uppsala (SE); **Mats Lundkvist**, Uppsala (SE)(73) Assignee: **GE HEALTHCARE BIO-SCIENCES AB**, Uppsala (SE)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/205,956**(22) Filed: **Jul. 8, 2016**(65) **Prior Publication Data**

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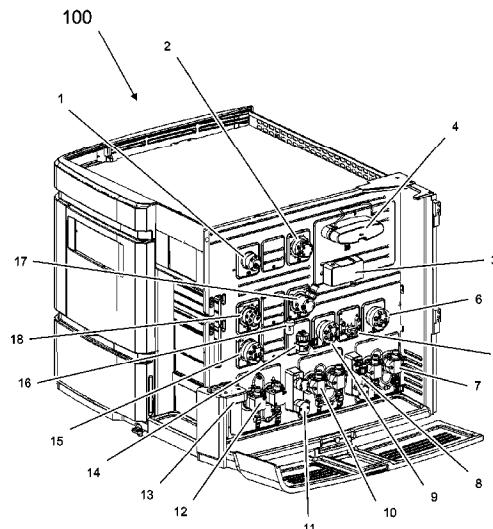
(60) Division of application No. 15/165,876, filed on May 26, 2016, which is a continuation of application No. (Continued)

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(51) **Int. Cl.**  
**B01D 35/00** (2006.01)  
**B01D 15/08** (2006.01)  
(Continued)(52) **U.S. Cl.**CPC ..... **G01N 35/1097** (2013.01); **B01D 15/10** (2013.01); **B01D 29/60** (2013.01);  
(Continued)(58) **Field of Classification Search**None  
See application file for complete search history.(56) **References Cited****U.S. PATENT DOCUMENTS**4,044,593 A 8/1977 Haruki et al.  
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(Continued)*Primary Examiner* — Richard Gurtowski(74) *Attorney, Agent, or Firm* — Arent Fox LLP(57) **ABSTRACT**

Automated fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components with an external fluidics section and an internal non fluidics section, and wherein the housing comprises a liquid handling panel with two or more of component positions for receiving said interchangeable modular components such that the external fluidics section is separated from the non fluidics section by the liquid handling panel.

**29 Claims, 10 Drawing Sheets**Shinoff  
7/22/2020  
**EX 121**

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**G01N 30/88** (2006.01)  
**B01D 29/60** (2006.01)  
**G01N 30/24** (2006.01)  
**G01N 30/38** (2006.01)  
**B01D 17/12** (2006.01)  
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**G01N 30/02** (2006.01)

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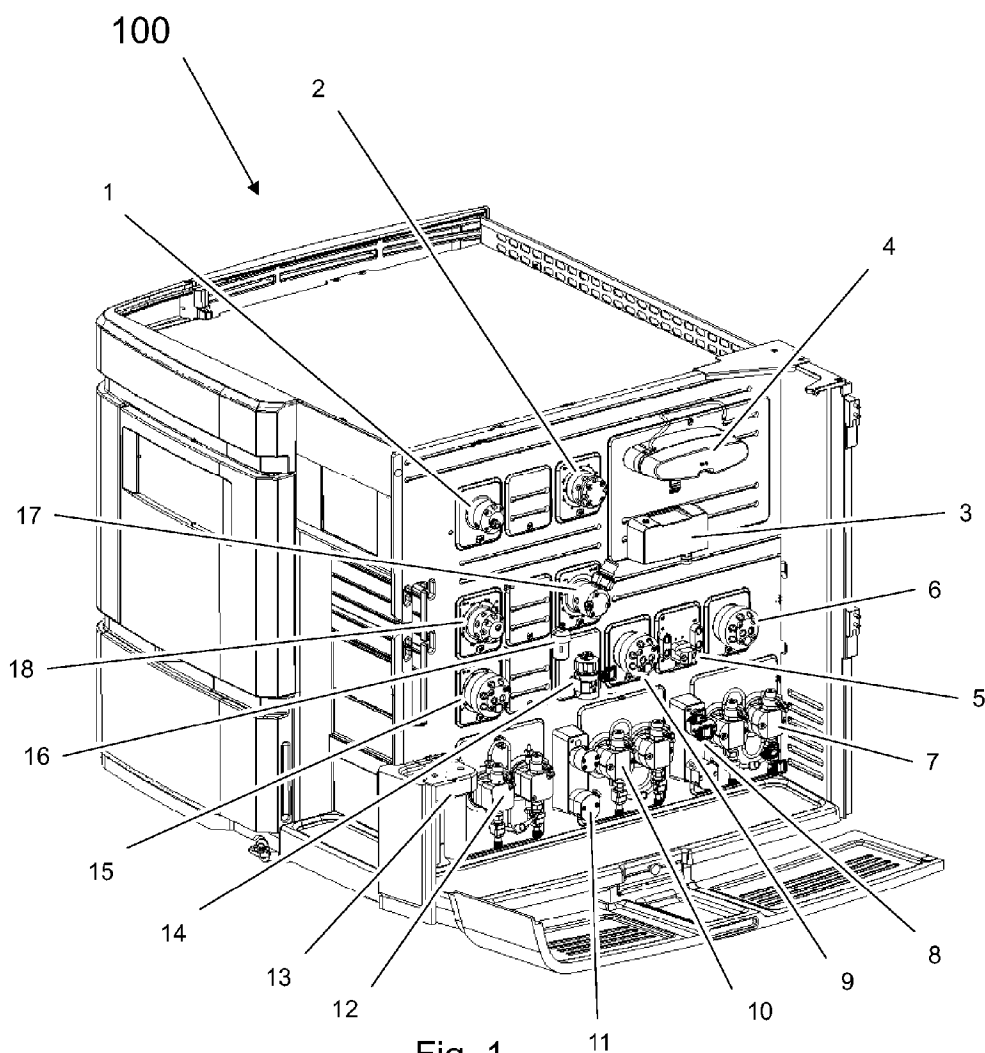


Fig. 1

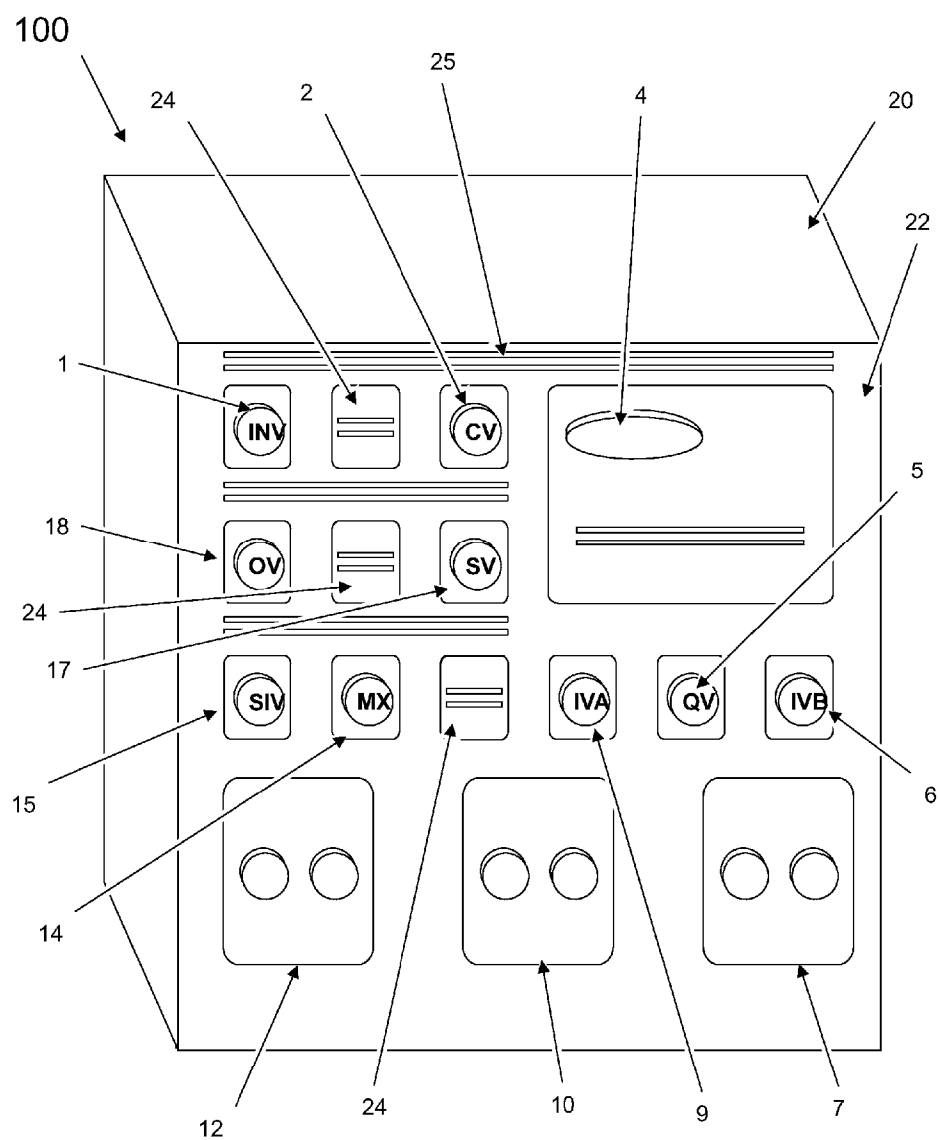


Fig. 2

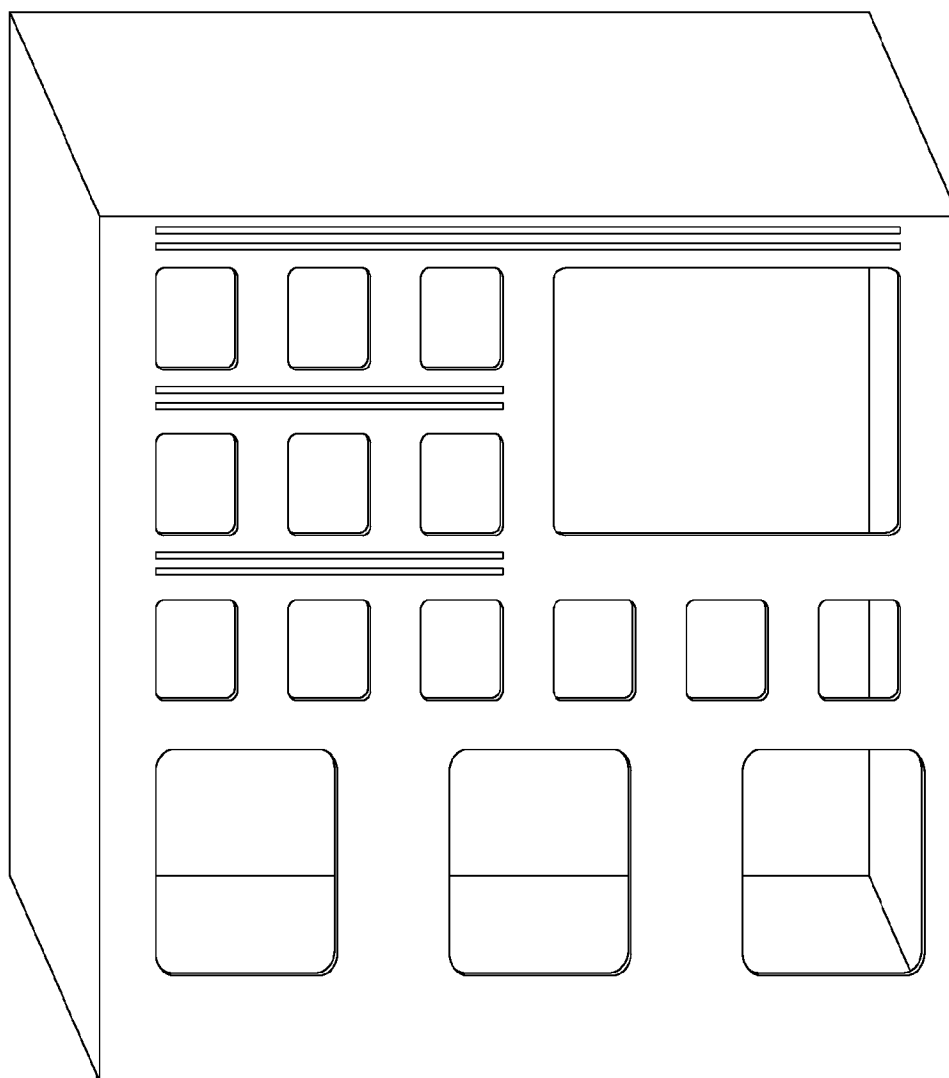


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**Fig. 3**

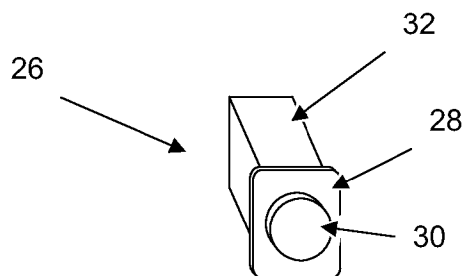


Fig. 4a

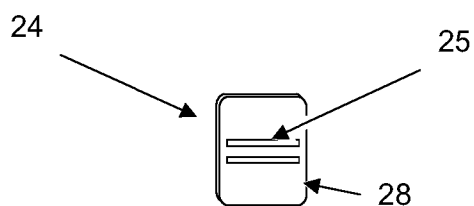


Fig. 4b

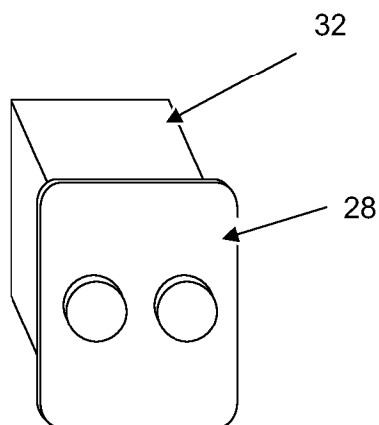


Fig. 4c

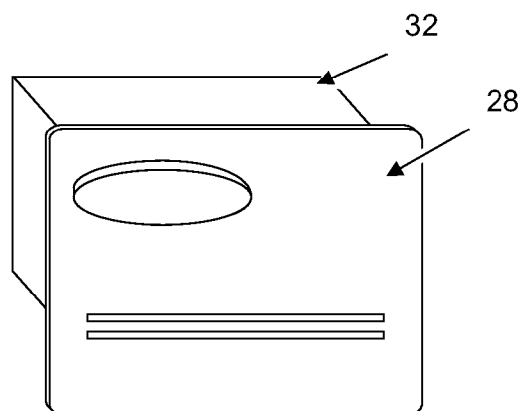


Fig. 4d

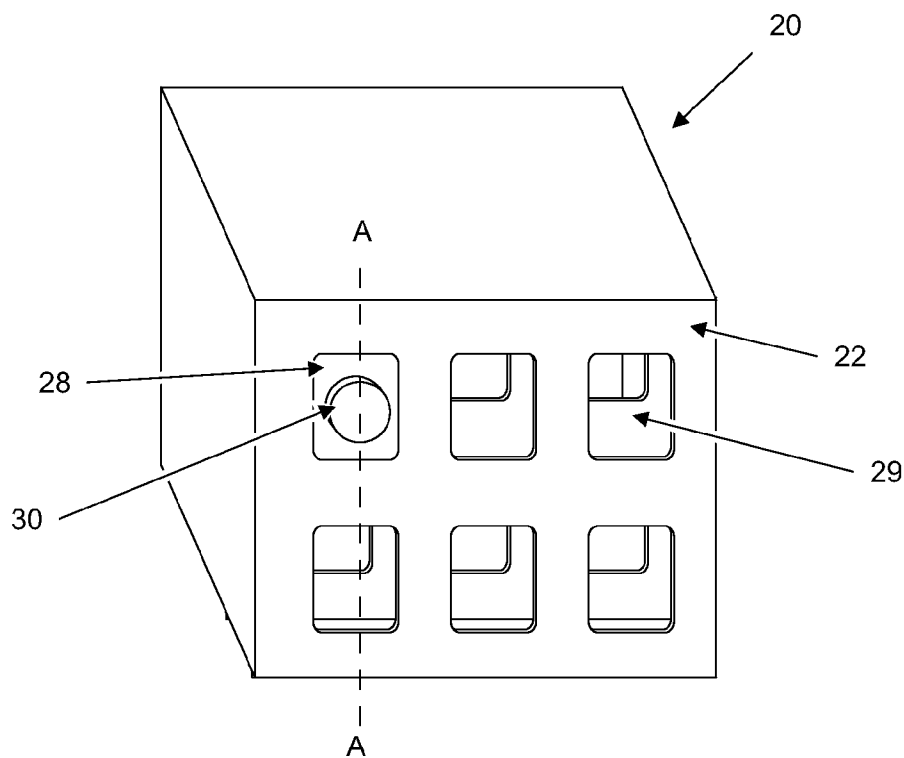


Fig. 5a

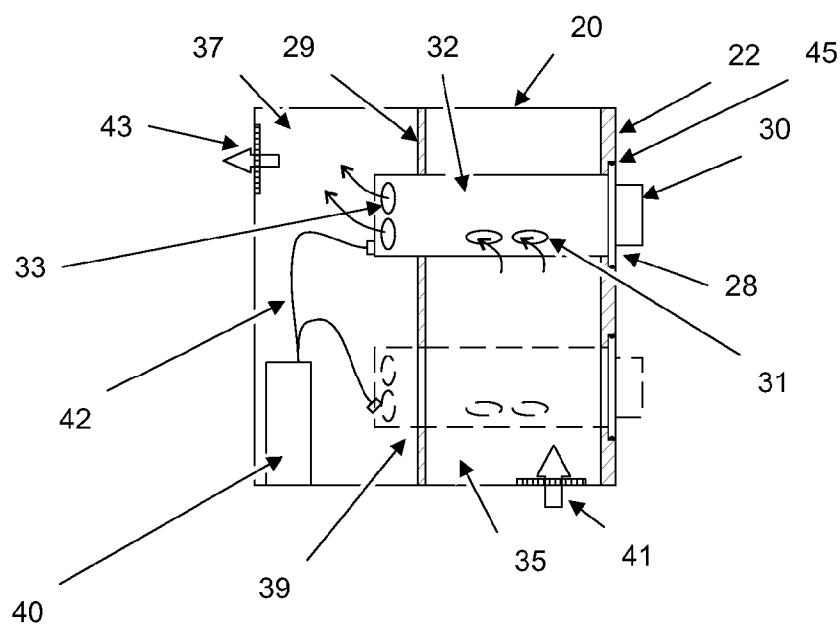


Fig. 5b

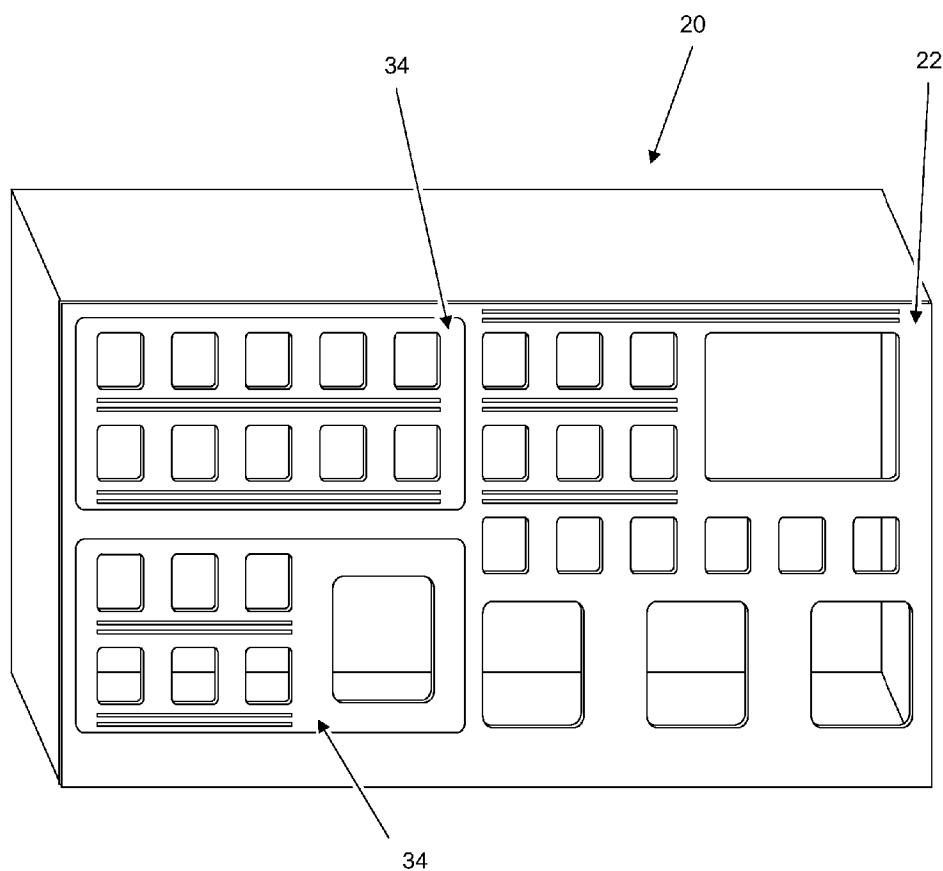


Fig. 6

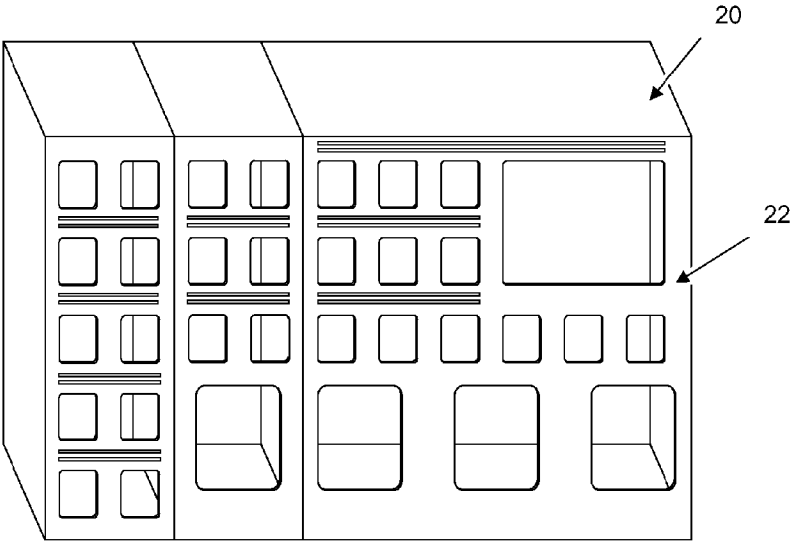


Fig. 7a

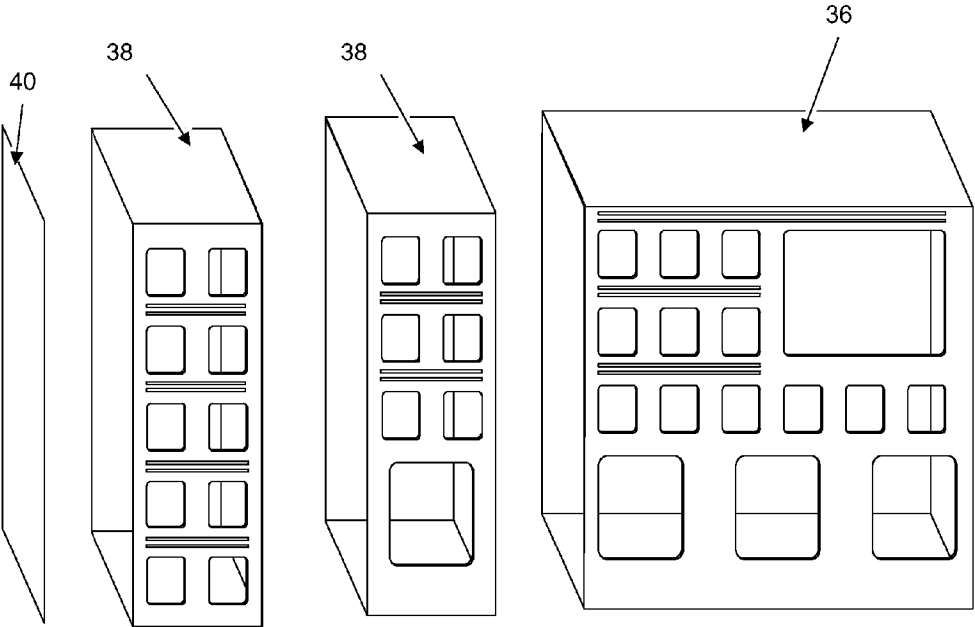
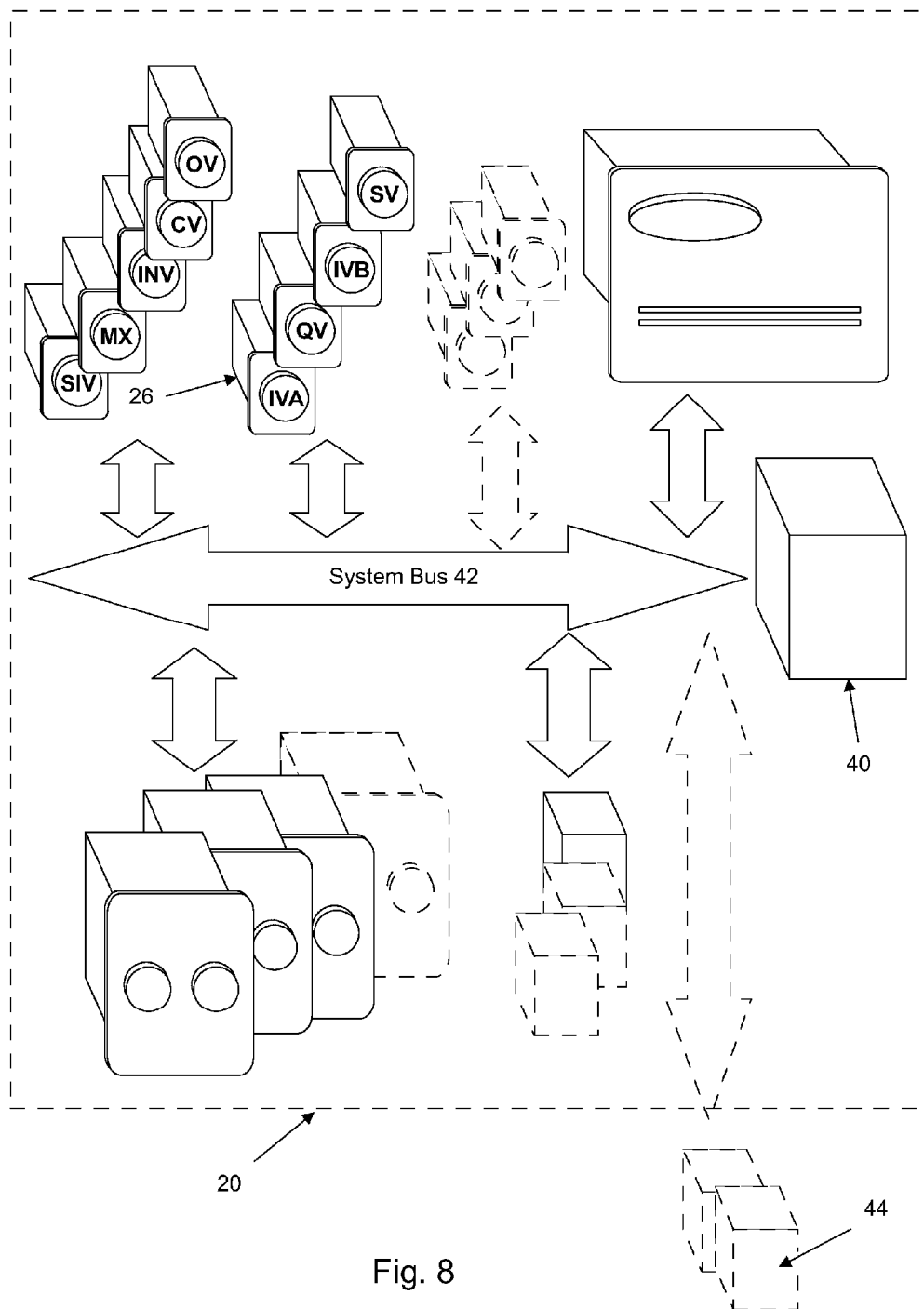


Fig. 7b



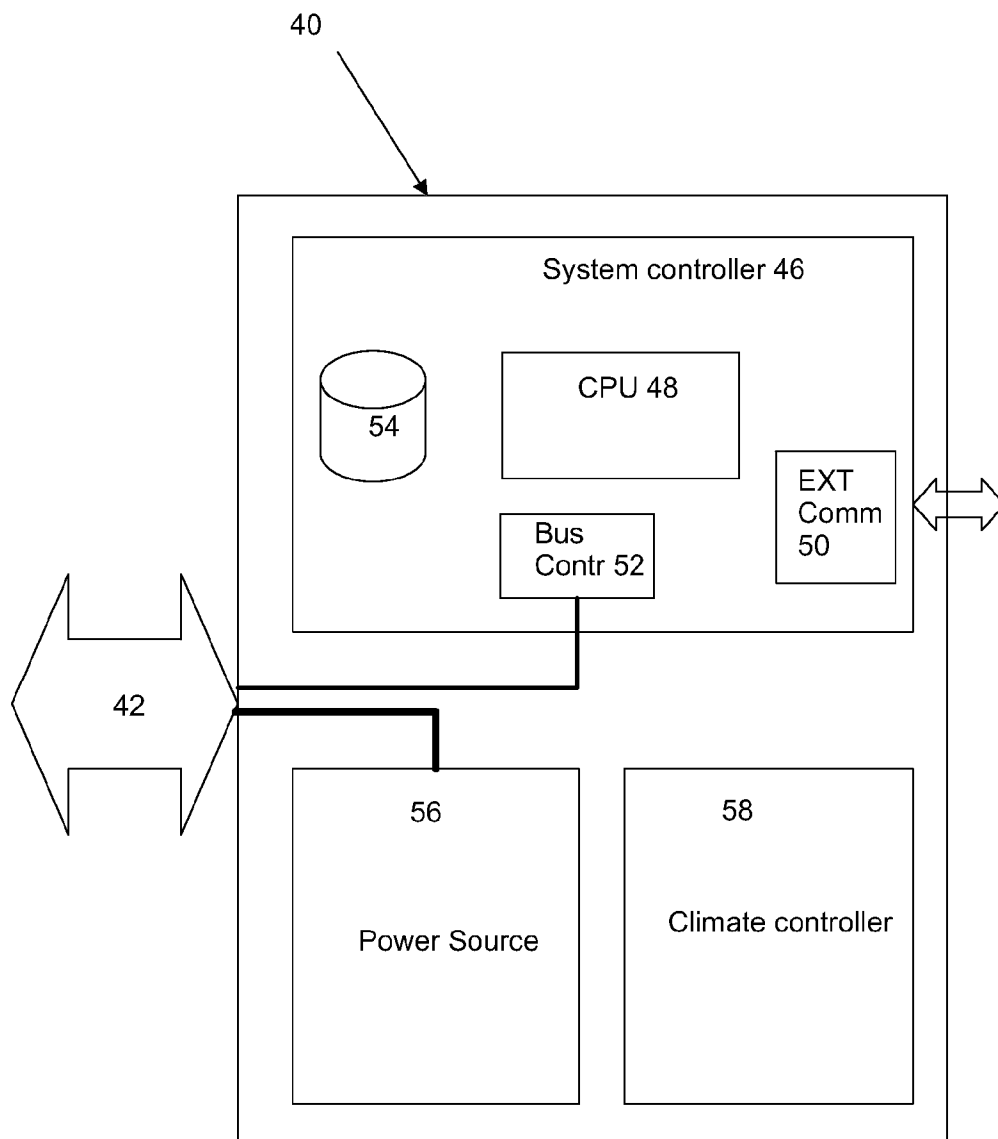


Fig. 9

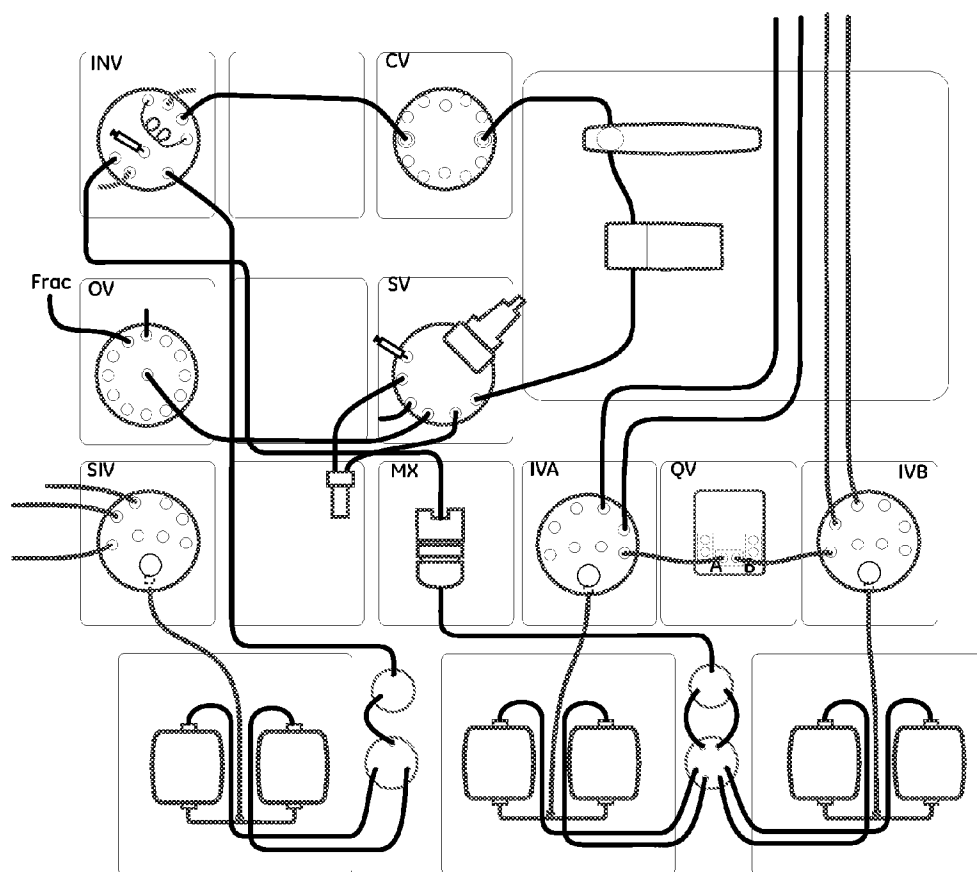


Fig. 10



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**AUTOMATED FLUID HANDLING SYSTEM****CROSS REFERENCE TO RELATED APPLICATION**

This application is a Divisional of U.S. patent application Ser. No. 15/165,876 filed May 26, 2016 which is a Continuation of U.S. patent application Ser. No. 14/463039 filed Aug. 19, 2014 which is a Continuation of U.S. patent application Ser. No. 13/376929 filed Dec. 8, 2011 which is a 35 U.S.C. 371 National Phase of International Patent Application No. PCT/SE2010/050624 filed Jun. 4, 2010 which claims priority to Swedish Patent Application No. 0950431-7 filed Jun. 9, 2009, the disclosure of these prior applications are hereby incorporated in their entirety by reference.

**BACKGROUND OF THE INVENTION**

The present invention relates to the art of fluid handling system systems, and in particular to an automat fluid handling system that is highly flexible and configurable. The fluid handling system may e.g. be a liquid chromatography system, a filtration system, a chemical synthesis system or the like.

There is a large range of fluid handling systems e.g. in laboratories. Such systems comprise a number of fluid handling units, e.g. one or more pumps, valves, mixers, sensor units etc of different types. Said fluid handling units are interconnected by fluid conduits in the form of, rigid or flexible tubes or the like. Even though some systems may be designed for a specific type of application with a specific flow path, there often exists a need for flexibility and ability to alter or optimize the fluid flow path of the system. Moreover, upgrading is often restricted to specific kits provided by the manufacturer, and upgrade kits often is supplied as external add-on equipment to be arranged besides the original system, thus enlarging the foot print of the system and that need to be connected to the system both fluidically and electrically (i.e. to a system control bus or the like). Moreover, replacement of defect fluid handling units is a time consuming and delicate task.

One type of liquid handling system is liquid chromatography systems which is a standard method in laboratories, and there are a broad range of liquid chromatography systems available on the market. Common to most of the present systems is the lack of flexibility in adapting the instrument to a variety of different applications.

**SUMMARY OF THE INVENTION**

The object of the invention is to provide a new fluid handling system, which system overcomes one or more drawbacks of the prior art. This is achieved by the fluid handling system as defined in the independent claims.

One advantage with such a fluid handling systems is that the system may easily be upgraded without need for add-on equipment, and that the flow path may be easily optimized for new experimental setups.

Embodiments of the invention are defined in the dependent claims.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The invention will be described in detail below with reference to the drawings, in which

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FIG. 1 shows one embodiment of a fluid handling system in the form of a liquid chromatography system, according to the present invention.

FIG. 2 is a schematic illustration of a housing with a liquid handling panel of the fluid handling system of FIG. 1.

FIG. 3 is a schematic illustration of the housing with the liquid handling panel of FIG. 2 with the modular components of the fluid handling system removed.

FIGS. 4a to 4d are schematic illustrations of examples of component modules of the fluid handling system removed.

FIGS. 5a and 5b show a schematic embodiment of an automated fluid handling system.

FIG. 6 is a schematic illustration of an embodiment of a housing with a modular liquid handling panel with the modular components of the fluid handling system removed.

FIGS. 7a and 7b are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with the modular components of the fluid handling system removed.

FIG. 8 is a schematic illustration of an embodiment of the system architecture of one embodiment of a fluid handling system according to the present invention.

FIG. 9 is a schematic illustration of an embodiment of a master control unit of one embodiment of a fluid handling system according to the present invention.

FIG. 10 is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel for the liquid chromatography system of FIG. 1.

**DETAILED DESCRIPTION OF THE INVENTION**

According to one embodiment, there is provided an automated fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components with an external fluidics section and an internal non fluidics section, and wherein the housing comprises a liquid handling panel with two or more of component positions for receiving said interchangeable modular components such that the external fluidics section is separated from the non fluidics section by the liquid handling panel.

According to another embodiment, there is provided a fluid handling system in the form of a liquid chromatography system comprising a housing, two or more high pressure pumps, at least one sensor unit and a plurality of fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components and the housing comprises a liquid handling panel with a plurality of component positions for receiving said modular components.

FIG. 1 shows one embodiment of an automated fluid handling system modular in the form of a liquid chromatography system, with a plurality of interchangeable modular components arranged in a liquid handling panel wherein the reference numbers denotes:

1. Injection valve
2. Column valve with integrated pressure sensors
3. Conductivity monitor
4. UV monitor
5. Quaternary valve
6. Inlet valve B with integrated air sensor
7. System pump
8. Pressure monitor, system pump
9. Inlet valve A with integrated air sensor
10. System pump

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11. Pressure monitor, sample pump
12. Sample pump
13. Rinsing system
14. Mixer with online filter
15. Sample inlet valve with integrated air sensor
16. Flow restrictor
17. pH valve
18. Outlet valve

The disclosed embodiment is supplied with three high precision pumps 7, 10, 12. There are two System pumps 7, 10, System pump A 10 and System pump B 7, and one Sample pump 12. The System pumps 7, 10 may be used individually, or in combination to generate isocratic or gradient elution in purification methods. The Sample pump 12 is dedicated for direct loading of sample onto a column, or for filling of sample loops.

#### Function of the Pumps:

Each pump module consists of two pump heads (not shown). The individual heads are identical but actuated in opposite phase to each other by individual stepper motors, controlled by a microprocessor. The two pistons and pump heads work alternately to give a continuous, low pulsation, liquid delivery. The flow rate of the two System pumps may be varied between about 0.001 ml/min and 25.000 ml/min and the maximum operating pressure is about 20 MPa. The flow rate of the Sample pump may e.g. be varied between 0.01 and 25 ml/min and according to one embodiment the maximum operating pressure is 10 MPa.

According to one embodiment, the plurality of fluid control valves of at least two different configurations are valves of rotary type. Such a motorized rotary valve may consist of a Valve head with a number of defined bores with channels to the inlet and outlet ports of the valve. The Rotary disc, mounted on the motor, has a number of defined channels. The pattern of channels of the Rotary disc together with the pattern and location of the ports of the Valve head, define the flow path and function of each type of valve. When the Rotary disc turns, the flow path in the valve changes.

One embodiment of fluid control valves are Inlet valves A and B (9, 6 respectively) that are used to select which buffers or samples to use in a run, and Sample inlet valve 15 that is located before Sample pump 12. Inlet valve A 9 is located before System pump A 10, Inlet valve B 6 is located before System pump B 10, and Sample inlet valve 15 is located before Sample pump 12. Inlet valve A and Inlet valve B are connected to another embodiment of a fluid control valve in the form of a Quaternary valve 5. The Quaternary valve is used for automatic buffer preparation, and for formation of quaternary gradients. The number of inlets can be increased by installing component modules with extra inlet valves. Inlet valve A and Inlet valve B enable automatic changing between different buffers and wash solutions, and can be used to generate gradients by mixing buffer A and buffer B. The air sensors integrated in Inlet valve A and Inlet valve B can be used to prevent introduction of air into the pumps and columns.

The Quaternary valve is used for automatic mixing of four different solutions. The Quaternary valve opens one inlet port at a time, and the different solutions are mixed in a Mixer 14 to form the desired buffer. The opening time in the switching valve is controlled by the system. The volume for each inlet port opening increases stepwise when the flow increases. To obtain a homogeneous buffer composition, one has to make sure to use a mixer chamber volume suitable for the flow rate of the method.

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The Quaternary valve can be used to create a gradient using four different solutions simultaneously in any combination. The percentage of each solution is controlled by instructions in the method. It is possible to form gradients that changes the percentage of two, three or four solutions linearly over time. This is useful when advanced methods are developed.

The Sample inlet valve 15 enables automatic loading of different samples when using the Sample pump 12 to inject sample directly onto the column or to fill a sample loop. The Sample inlet valve has an inlet dedicated for buffer. This Buffer inlet is used in methods to fill the Sample pump with solution before sample is introduced. The Buffer inlet is also used to wash the Sample pump with buffer between runs. The air sensor integrated in the Sample inlet valve is e.g. used when sample is applied from a vessel onto a column by selecting Inject all sample using air sensor in the Sample application phase of a method. This function uses the Buffer inlet is used to finalize sample injection and to remove air from the Sample pump.

Still another embodiment of fluid control valve may be an Injection valve 1, which is used to direct sample onto the column. The valve enables usage of a number of different sample application techniques. A sample loop can be connected to the Injection valve and filled either automatically using the Sample pump or manually using a syringe. The sample can also be injected directly onto the column using the Sample pump.

Still another embodiment of fluid control valve may be a Column valve 2 that is used for connection of columns to the system, and to direct the flow onto the column. Up to five columns can be connected to the disclosed embodiment of said valve simultaneously. The valve also has a built-in bypass capillary that enables bypassing of connected columns.

The number of column positions can be increased by installing an extra Column valve. Both top and bottom of each column shall be connected to the Column valve. The top of the column shall be connected to one of the A ports (e.g., 1A), and the bottom of the column shall be connected to the corresponding B port (e.g., 1B). The flow direction can be set either from the top of the column to the bottom of the column, Down flow, or from the bottom of the column to the top of the column, Up flow. In the default flow path of the Column valve the columns are bypassed. Pressure monitors that measures the actual pressure over the column are integrated into the inlet and outlet ports of the Column valve.

Still another embodiment of fluid control valve may be a pH valve 17 that has an integrated flow cell where a pH electrode can be installed. This enables in-line monitoring of pH during the run. A flow restrictor is connected to the pH valve and can be included in the flow path to generate a backpressure high enough to prevent formation of air bubbles in the UV flow cell. The pH valve is used to direct the flow to the pH electrode and to the flow restrictor, or to bypass one or both.

Still another embodiment of fluid control valve may be an Outlet valve 18 that is used to direct the flow to a Fraction collector (not shown), to any of e.g. 10 outlet ports, or to waste. The number of outlets can be increased by installing an extra Outlet valve.

A Mixer 14 may e.g. be located after System pump A and System pump B and before the Injection valve. The purpose of the Mixer is to make sure that the buffers from the System

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pumps are mixed to give a homogenous buffer composition. The Mixer has a built-in filter that prevents impurities from entering the flow path.

To fulfill a desired purpose, with the disclosed liquid chromatography system it is possible to adapt and extend the flow path in a simple and a flexible way. Up to three extra fluid control valves or the like can be installed using the free valve positions. Dummy modules are installed in these positions at delivery. To obtain an optional flow path, it is also possible to move the standard fluid control valves to other positions. There are also two types of extra air sensors available which can be installed before Sample inlet valve or after Injection valve.

In the configuration disclosed in FIG. 1, 7 inlets are available for each inlet valve. To increase the number of inlets, an extra inlet valve can be installed which increases the number of inlets to 14 for one of the valves. This optional configuration can be convenient for example when a larger number of samples will be used. There is also a general type of inlet valve, Valve X, which can be used to increase the number of inlets to for example the Quaternary valve.

In the configuration disclosed in FIG. 1 with one column valve, 5 column positions are available. To increase the number of column positions to 10, an additional column valve can be installed in the instrument. An application can be to evaluate a number of different columns in method optimization.

In the configuration disclosed in FIG. 1 with one outlet valve, 10 outlet positions are available. To increase the number of outlets, one or two extra outlet valves can be connected, adding up to a total of 21 or 32 outlet positions. This optional configuration is convenient when collecting a number of large fractions outside the fraction collector.

Optional modules are easy to install in the disclosed modular liquid chromatography system. The dummy module is removed with a hexagon wrench and a bus cable is disconnected. The bus cable is connected to the optional fluid control valve or the like which is assembled in the instrument. The module is then added to the System properties in the control software. The available optional modules may e.g. be pre-configured to give the desired function. However, the function of a valve may e.g. be changed by changing the Node ID.

FIG. 2 is a schematic illustration of a housing 20 with a liquid handling panel 22 of the fluid handling system in the form of a modular liquid chromatography system 100 of FIG. 1. In FIG. 2 some components have been removed for clarity reasons. In the disclosed configuration, as disclosed in detail above, the modular liquid chromatography system 100 comprises a plurality of fluid control valves in the form of: Injection valve 1, Column valve 2, Quaternary valve 5, Inlet valve B 6, Inlet valve A 9, Sample inlet valve 15, pH valve 17, and Outlet valve 18. The chromatography system 100 further comprises UV monitor 4, System pump B 7, System pump A 10, Sample pump 12, Mixer 14, and three Dummy modules 24. According to one embodiment, all liquid handling components and sensors arranged at the liquid handling panel 22 are designed to be readily interchangeable. The interchangeability provides improved service and upgrade possibilities and also a possibility to customize the positions of the respective liquid handling components, such as the fluid control valves, e.g. in order to optimize the fluid path for a specific experimental setup. As is illustrated in FIG. 2, there are three large component positions e.g. for pump modules, one UV-sensor position and 9 standard component positions, e.g. for fluid control valves or the like. The component positions are given a

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standardized size and shape to provide simple interchangeability. According to one embodiment, each modular component is retained in a mating component position by a single screw, and it is connected to the master control unit by a single bus cable providing both communication and system power to each component. FIG. 3 is a schematic illustration of the housing with the liquid handling panel of FIG. 2 with the modular components of the liquid chromatography system removed.

FIGS. 4a to 4d are schematic illustrations of examples of fluid handling units in the form of modular component of the fluid handling system removed. FIG. 4a shows a standard interchangeable modular component 26, e.g. a fluid control valve or the like. The standard component module 26 comprises a panel member 28, an external fluidics section 30 and an internal non-fluidics section 32. According to one embodiment, the panel member 28 essentially separates the fluidics in the external fluidics section 30 from electronics and control means in the internal non-fluidics section 32.

FIG. 4b shows a Dummy module 24, which is intended to be placed in non used standard component positions. In the disclosed embodiment, the Dummy modules are provided with mounting grooves for attachment of accessories to the system. In the disclosed embodiment the dummy module is shown as a panel member 28 without any internal section. FIGS. 4c and 4d shows a pump module and an UV-module, respectively, each having an external fluidics section 30 and an internal non-fluidics section 32.

As is disclosed in FIGS. 4a to 4d, the interchangeable modular components 26 comprises a panel member arranged to separate the fluidics section from the non fluidics section and for attachment to a component position in the liquid handling panel. Said panel attachment member may be arranged so that all fluid connections of said modular component are arranged on a wet side of the panel attachment member separating them from electrical components that are arranged on a dry side thereof, hence providing a high degree of liquid resistance at the external part of the fluid handling panel, and so that the liquid resistance requirements for the internal sections may be somewhat lightened. According to one embodiment, the interchangeable modular components are sealed against the liquid handling panel by a sealing member. According to another embodiment, not shown, the modular component does not comprise any panel member, but there is provided a suitable sealing arrangement between the component position openings of the liquid handling panel and the external surface of the interchangeable modular components 26. In the disclosed embodiments, the component position openings of the liquid handling panel and the interchangeable modular components 26 are shown to have an essentially rectangular crosssectional shape, but other shapes may be equally applicable. According to one embodiment, there is provided a general fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components as is schematically disclosed in FIG. 5a. As discussed above such a system may be configured for essentially any type of automated liquid handling operations provided that suitable fluid handling units are provided as interchangeable modular components for the system. According to one embodiment there is provided an automated fluid handling system comprising at least one fluid pump, at least one sensor unit and two or more fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components.

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The liquid handling panel **22** of the fluid handling system may e.g. be designed in any suitable manner to allow the modular components to be arranged in an efficient manner.

FIGS. **5a** and **5b** shows a schematic embodiment of an automated fluid handling system wherein the housing **20** comprises an internal climate panel **29** arranged at a distance behind the liquid handling panel **22** defining an air inlet compartment **35** and air outlet compartment **37** in the housing **20**, the climate panel **29** being provided with complementary component positions **39** for receiving the internal non fluidics section **32** of the interchangeable modular components **26**, and wherein the non-fluidics section **32** of at least one interchangeable modular component is provided with one or more air inlet openings **31** located in the air inlet compartment **35** and one or more air outlet openings **33** located in the air outlet compartment **37** when the interchangeable modular component arranged in position in the component position. FIG. **5b** shows the fluid handling system of FIG. **5a** in a schematic cross sectional view. As is indicated by inlet vent **41** and outlet vent **43**, air for cooling interchangeable modular components **26** provided with air inlet and outlet openings **31**, **33** is preferably arranged to enter the air inlet compartment **35** at a distance from the outlet vent **43** in order to avoid recirculation of air. The air circulation in the system may be achieved by a system cooling unit (not shown) providing a flow of air from the air inlet compartment **35** to the air outlet compartment **37**, through the at least one interchangeable modular component **26**. Alternatively, the at least one interchangeable modular component **26** is provided with a local cooling unit (not shown) providing a flow of air from the air inlet compartment **35** to the air outlet compartment **37**. As is indicated, the complementary component positions **39** are arranged to provide a relatively air flow tight fit with respect to the internal non fluidics section **32** of the interchangeable modular components **26**, and according to one embodiment, this may be achieved by a sealing arrangement. In FIG. **5b**, there is shown a sealing member **45** for sealing the interchangeable modular components **26** with respect to the liquid handling panel **22**, as discussed above. Other sealing member arrangements may be envisaged by a person skilled in the art. According to one embodiment, fluids are strictly restricted to the fluidics section **30** of the interchangeable modular component **26**, but in alternative embodiments, only fluid connections are restricted to the fluidics section **30** allowing fluid to "cross" the fluid handling panel inside the non-fluidics section **30** of the interchangeable modular component **26**.

In FIG. **5b** there is further shown a master control unit **40** and buss connectors **42** for connecting the interchangeable modular components **26** to the master control unit **40**. According to one embodiment, the component positions including the buss connectors **42** and the interchangeable modular components **26** are of plug and play configuration with respect to each other.

FIG. **6** is a schematic illustration of an embodiment of a housing **20** with a modular liquid handling panel **22** with the modular components of the liquid chromatography system removed. In the disclosed embodiment, also the layout of the liquid handling panel **22** is configurable by means of two interchangeable panel sections **34** which may be selected in accordance with the desired layout of the system. In FIG. **6** two different layouts of the interchangeable panel sections are disclosed, but the layout may include any suitable configuration.

FIGS. **7a** and **7b** are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with

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the modular components of the liquid chromatography system removed. In the disclosed embodiment, the modular housing is comprised of a main housing **36** that comprises the master control unit including power supply and climate control for the whole housing, two expansion housing modules **38** and a side member **40**. This approach provides very flexible expansion possibilities for the chromatography system, while preserving the benefits of a single master control unit including power supply and climate control.

FIG. **8** is a schematic illustration of an embodiment of the system architecture of one embodiment of a modular liquid chromatography system according to the present invention. As mentioned above, the chromatography system may comprise a master control unit **40** arranged to communicate with all modular components e.g. **1-26**, over a system bus **42** such as a CAN-bus or the like. In one embodiment, each modular component is provided with a dedicated CPU unit allowing the component to independently perform operations in response to instructions over the BUS **42**. In order to minimize the number of connectors to be attached to each modular component, the bus **42** further comprises power feed for the modular components. The Bus **42** may be connected to any suitable number of modular components arranged in the housing **20**, but also to one or more modular components **44** outside of the housing **20** or the like. As is mentioned briefly above, the master control unit may further be arranged to control the climate in the housing. In addition to the disclosed modular components, other components of the chromatography system, e.g. a fraction collector or the like, may be arranged in the housing and the controlled climate therein.

According to one embodiment, different component modules are automatically identified by the master control unit, whereby they may be moved essentially freely between different positions. Moreover, the master control unit may be arranged to provide said information to Chromatography control software whereby experimental setup and planning may be performed. In one embodiment, the control system may be arranged to provide an optimized layout of the component modules with respect to the present layout of the liquid handling panel and available component modules for a specific experimental setup.

According to one embodiment, the interchangeable panel sections **34** of FIG. **5** and the expansion housing modules **38** of FIGS. **6a** and **6b** may be provided with means for automatic detection of the same to allow automatic configuration of the system by the master control unit **40**. In one embodiment, each interchangeable panel section **34** and expansion housing module **38** comprises a hub (not shown) for connection to the system bus **42** in order to expand the system bus **42** network to the number of component modules in each interchangeable panel section **34** or expansion housing module **38**.

FIG. **9** is a schematic illustration of an embodiment of a master control unit of one embodiment of a modular liquid chromatography system according to the present invention. The master control unit **40** comprises a system controller **46** for communicating with internal and external components and control computers (not shown) etc. According to one embodiment, the system controller comprises a suitable CPU **48**, a bus controller **52**, an external communications controller **50**, such as a LAN unit, and a storage device **54**. The bus controller **52** is providing communication with the component modules. The master control unit may further comprise a Power supply **56** and a climate controller **58** arranged to keep the internal climate in the housing **20** at a predetermined level as discussed above.



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FIG. 10 is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel. Taking into account the complexity of the disclosed interconnection arrangement, the benefit of optimizing the fluid paths in alternative configurations of the system becomes evident. The task of optimizing the fluid paths may e.g. be performed to reduce the total length/volume of the fluid paths/tubing arranged to interconnect the different component modules in the system. Alternatively the optimization may be performed to minimize the length/volume of one or more specific fluid paths, such as the sample output path from the column to the fraction collector, in order to minimize dispersion of the fractionized sample.

The invention claimed is:

1. An automated liquid chromatography system comprising:

a housing;

a master control unit connected to a system bus; and two or more fluid handling units arranged as interchangeable modular components comprising (i) an external fluidics section, (ii) an internal non-fluidics section including a bus connector for directly connecting the interchangeable modular component with the system bus, and (iii) a panel member arranged to separate the fluidics section from the non-fluidics section,

wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing,

wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus,

wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus,

wherein the master control unit is arranged to automatically identify interchangeable modular components,

wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components, and

wherein the system is capable of performing automated liquid chromatography.

2. The chromatography system of claim 1, wherein the interchangeable modular components are sealed against the liquid handling panel by a sealing member.

3. The chromatography system of claim 1, wherein all interchangeable modular components are of same size.

4. The chromatography system of claim 1, wherein the interchangeable modular components are of two or more sizes.

5. The chromatography system of claim 1, wherein the at least two fluid control valves are arranged as interchangeable modular components.

6. The chromatography system of claim 1, wherein at least one of said interchangeable modular components further comprises a local cooling unit.

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7. The chromatography system of claim 1, wherein the housing includes at least four component receiving positions.

8. The chromatography system of claim 1, wherein the system includes at least one dummy component arranged in a component receiving position not occupied by any one of said interchangeable modular components.

9. The chromatography system of claim 1, wherein the system includes at least two fluid pumps.

10. The chromatography system of claim 1, wherein the component receiving positions are arranged in a two dimensional array.

11. The chromatography system of claim 7, wherein the at least four component receiving positions are arranged in a two dimensional array.

12. The chromatography system of claim 1, wherein the system further comprises a pH electrode that is external to the housing.

13. The chromatography system of claim 1, wherein the fluidics section of each interchangeable modular component comprises one or more fluid connectors for connecting the fluid handling unit to a liquid chromatography fluid path and wherein all fluid connectors are on a wet side of the panel member.

14. The chromatography system of claim 13, wherein the liquid chromatography fluid path is reconfigurable by moving the interchangeable modular components freely between the component receiving positions.

15. The chromatography system of claim 1, wherein the system further comprises at least one expansion housing module arranged to be attached to the housing and for accommodating additional interchangeable modular components at the liquid handling panel.

16. The chromatography system of claim 15, wherein the master control unit is arranged to automatically detect said at least one expansion housing module and to perform automatic configuration of the system.

17. An automated liquid chromatography system comprising:

a housing;

a master control unit connected to a system bus; and two or more fluid handling units arranged as interchangeable modular components comprising (i) an external fluidics section, (ii) an internal non-fluidics section including a bus connector for directly connecting the interchangeable modular component with the system bus, and (iii) a panel member arranged to separate the fluidics section from the non-fluidics section,

wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing,

wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus,

wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus,

wherein the master control unit is arranged to automatically identify interchangeable modular components,

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wherein said housing is adapted to accommodate the following units: two double piston pumps, one injection valve for injecting sample onto a column connecting a flow path of the liquid chromatography system, a UV monitor, and a mixer, wherein the double piston pumps, the injection valve, the UV monitor, and the mixer are interchangeable modular components; and wherein the system is capable of performing automated liquid chromatography.

18. The chromatography system of claim 17, wherein the double piston pumps are configured to provide a flow rate between 0.001 ml/min and 25 ml/min.

19. The chromatography system of claim 17, wherein the system further comprises a column valve comprising pressure sensors integrated into inlet and outlet ports of the column valve for measuring the actual pressure over the connected column.

20. The chromatography system of claim 17, which further comprises a sample inlet valve.

21. The chromatography system of claim 17, which further comprises a conductivity monitor.

22. The chromatography system of claim 17, which further comprises at least one expansion housing module arranged to be attached to the housing and for accommodating additional interchangeable modular components at the liquid handling panel.

23. The chromatography system according to claim 22, wherein the master control unit is arranged to automatically detect said at least one expansion housing module and to perform automatic configuration of the system.

24. The chromatography system according to claim 1, wherein the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, an outlet valve or any combination thereof.

25. The chromatography system according to claim 5, wherein the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, an outlet valve or any combination thereof.

26. The chromatography system according to claim 12, wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component.

27. The chromatography system according to claim 26, wherein the pH valve includes an integrated flow cell for in-line monitoring of pH levels.

28. The chromatography system of claim 1, wherein the system includes two double piston pumps, one injection valve for injecting a sample onto a column connected to a

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flow path of the liquid chromatography system, a UV monitor, a mixer, a pH-valve with an integrated flow cell for in-line monitoring of pH levels, and a quaternary valve for automatic buffer preparation and formation of quaternary gradients, wherein the double piston pumps, injection valve, monitor, mixer, pH valve, and quaternary valve are interchangeable modular components.

29. An automated liquid chromatography system comprising

a housing;

a master control unit connected to a system bus; and

two or more fluid handling units arranged as interchangeable modular components comprising (i) an external fluidics section, (ii) an internal non-fluidics section including a bus connector for directly connecting the interchangeable modular component with the system bus, and (iii) a panel member arranged to separate the fluidics section from the non-fluidics section,

wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non fluidics section is internal to the housing.

wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus,

wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus,

wherein the master control unit is arranged to automatically identify interchangeable modular components, and

wherein the system includes the following interchangeable modular components: two double piston pumps, a sample pump, two inlet valves for selecting inlet fluid to a respective pump, one injection valve for injecting sample onto a column connected to a flow path of the liquid chromatography system, a column valve for connecting one of a plurality of columns to the flow path, a UV-monitor, a mixer, a pH-valve with an integrated flow cell for in-line monitoring of pH levels, and a quaternary valve for automatic buffer preparation and for formation of quaternary gradients.

\* \* \* \* \*

# EXHIBIT 35



US009671420B2

(12) **United States Patent**  
**Blomberg et al.**

(10) **Patent No.:** **US 9,671,420 B2**  
(45) **Date of Patent:** **\*Jun. 6, 2017**

(54) **AUTOMATED FLUID HANDLING SYSTEM**

(58) **Field of Classification Search**

(71) Applicant: **GE HEALTHCARE BIO-SCIENCES AB**, Uppsala (SE)

None

See application file for complete search history.

(72) Inventors: **Johan Blomberg**, Uppsala (SE); **Mats Lundkvist**, Uppsala (SE)

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(73) Assignee: **GE HEALTHCARE BIO-SCIENCES AB**, Uppsala (SE)

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(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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This patent is subject to a terminal disclaimer.

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*Primary Examiner* — Richard Gurtowski

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(74) *Attorney, Agent, or Firm* — Arent Fox LLP

(30) **Foreign Application Priority Data**

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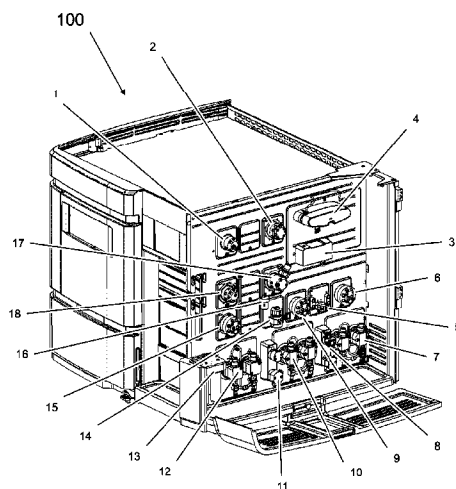
(57) **ABSTRACT**

(51) **Int. Cl.**  
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**B01D 15/08** (2006.01)  
(Continued)

Automated fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components with an external fluidics section and an internal non fluidics section, and wherein the housing comprises a liquid handling panel with two or more of component positions for receiving said interchangeable modular components such that the external fluidics section is separated from the non fluidics section by the liquid handling panel.

(52) **U.S. Cl.**  
CPC ..... **G01N 35/1097** (2013.01); **B01D 15/10** (2013.01); **B01D 29/60** (2013.01);  
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**30 Claims, 10 Drawing Sheets**



Shinoff  
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**EX 118**



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## Related U.S. Application Data

No. 14/463,039, filed on Aug. 19, 2014, now Pat. No. 9,404,902, which is a continuation of application No. 13/376,929, filed as application No. PCT/SE2010/050624 on Jun. 4, 2010, now Pat. No. 8,821,718.

## (51) Int. Cl.

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**G01N 35/10** (2006.01)  
**B01D 15/10** (2006.01)  
**G01N 30/88** (2006.01)  
**B01D 29/60** (2006.01)  
**G01N 30/24** (2006.01)  
**G01N 30/38** (2006.01)  
**B01D 17/12** (2006.01)  
**G01N 35/00** (2006.01)  
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CPC ..... **G01N 30/24** (2013.01); **G01N 30/38** (2013.01); **G01N 30/88** (2013.01); **B01D 15/08** (2013.01); **B01D 17/12** (2013.01); **B01D 2201/54** (2013.01); **G01N 2030/027** (2013.01); **G01N 2030/8804** (2013.01); **G01N 2030/8881** (2013.01); **G01N 2035/00326** (2013.01); **Y10T 137/6416** (2015.04); **Y10T 137/6525** (2015.04); **Y10T 137/6851** (2015.04); **Y10T 137/85986** (2015.04); **Y10T 137/87885** (2015.04)

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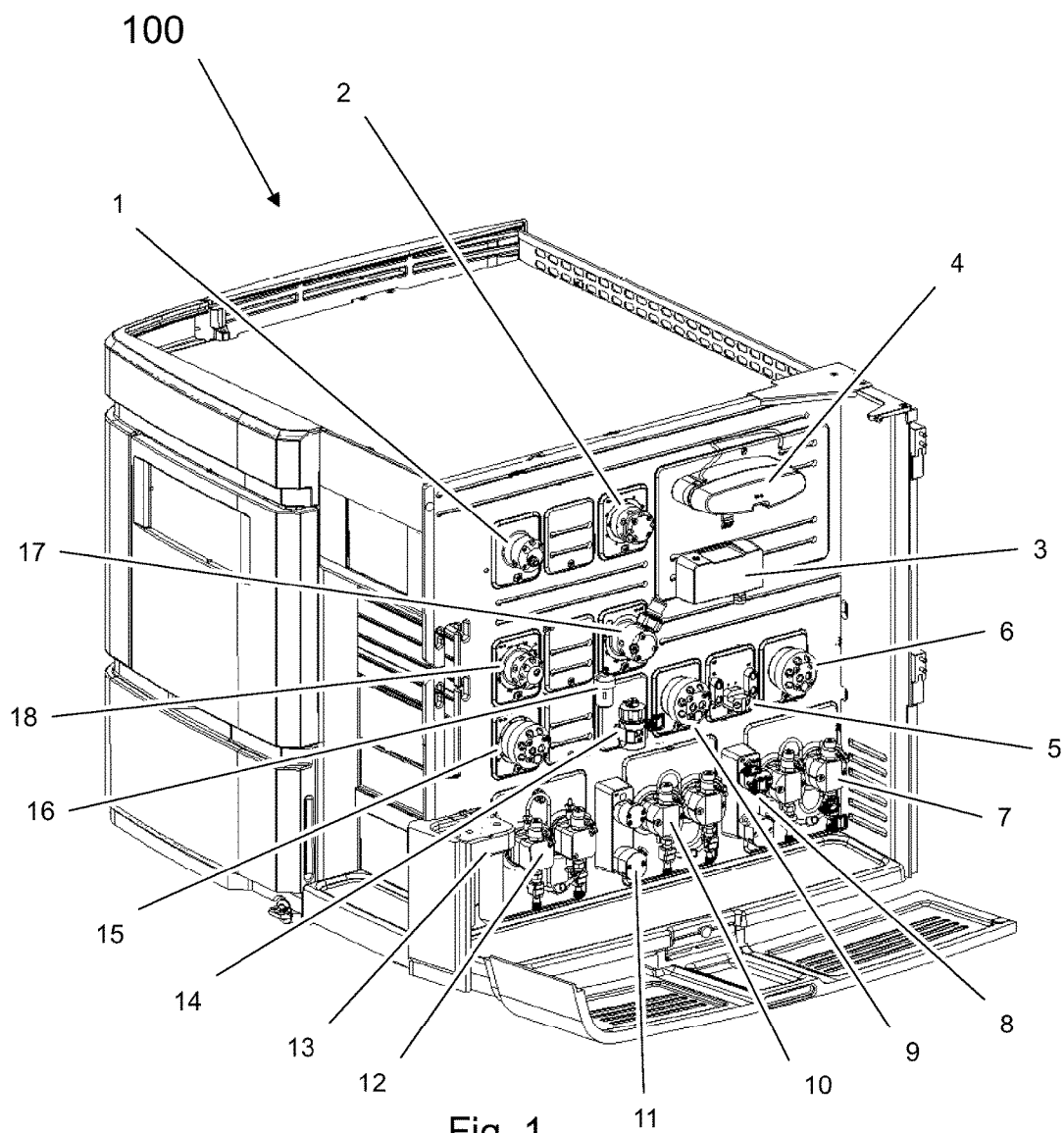


Fig. 1

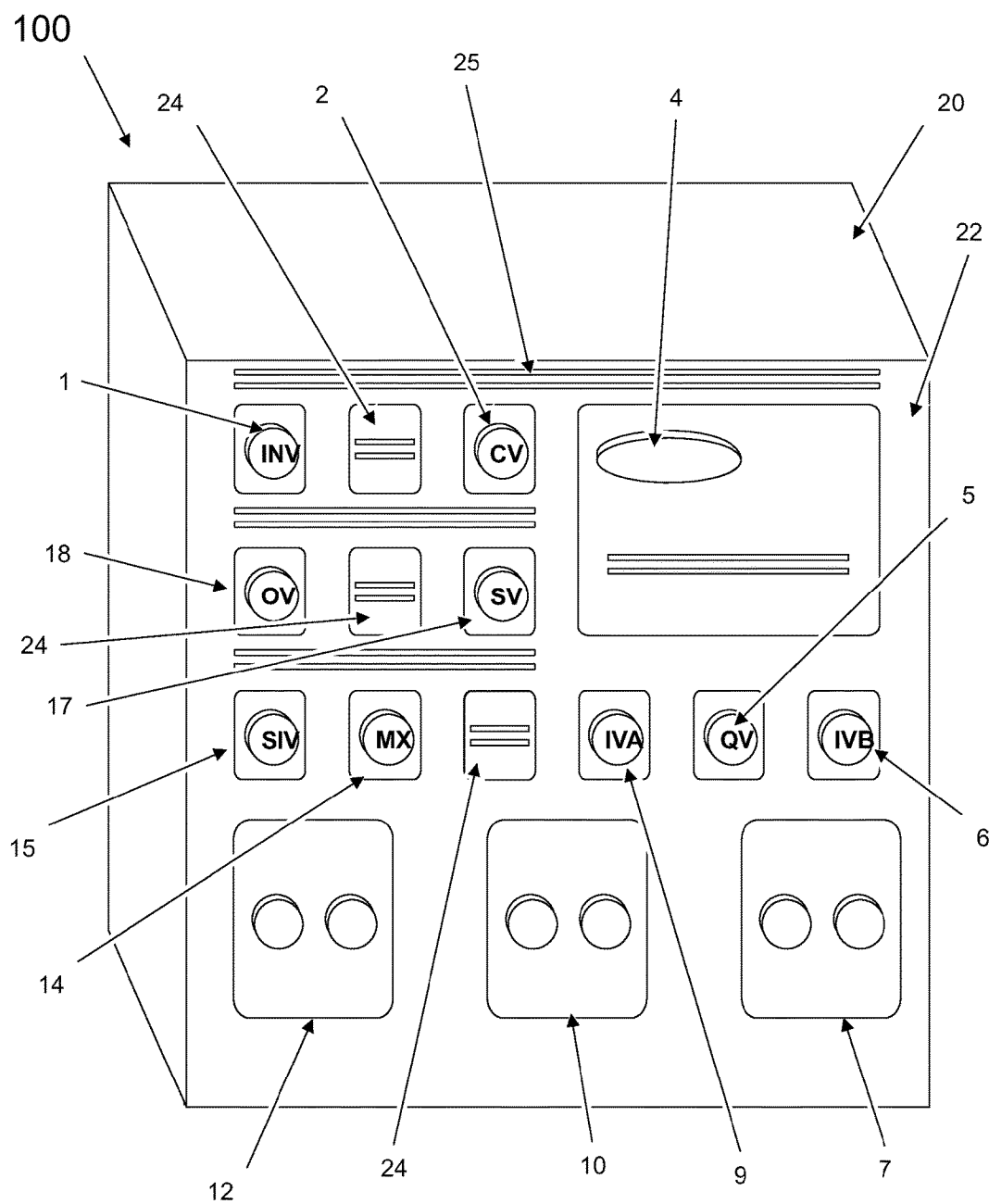


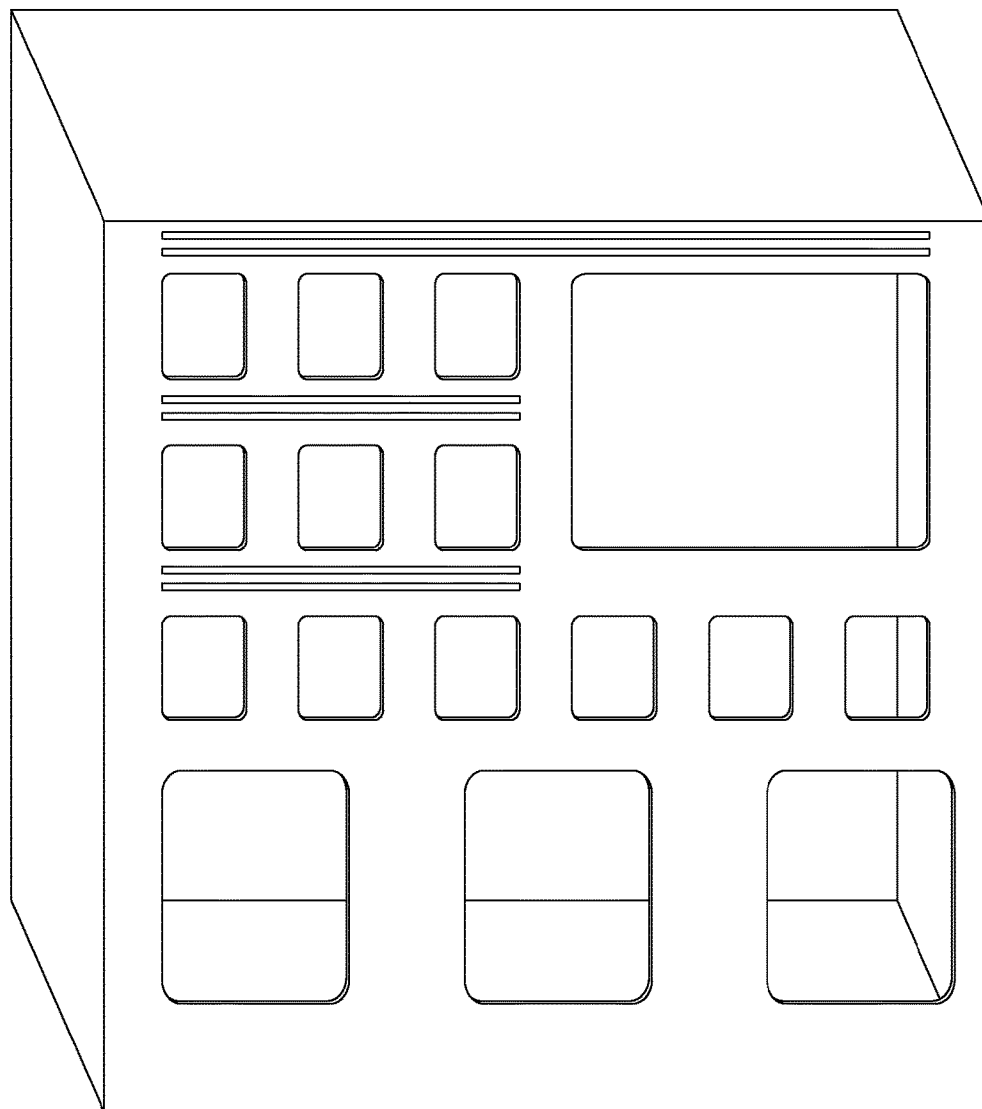
Fig. 2

**U.S. Patent**

**Jun. 6, 2017**

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**Fig. 3**

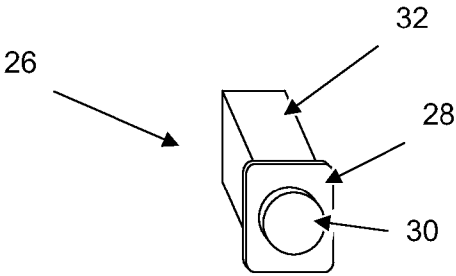


Fig. 4a

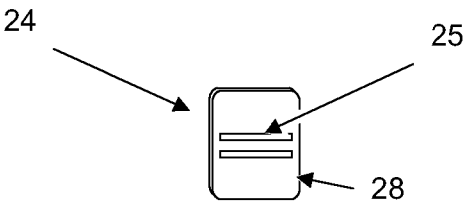


Fig. 4b

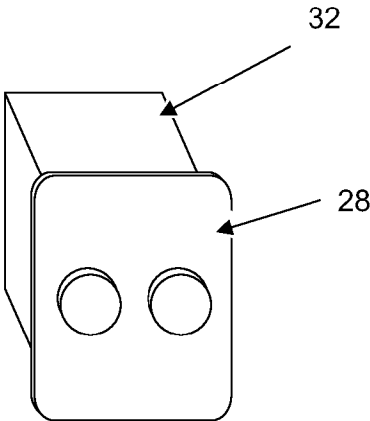


Fig. 4c

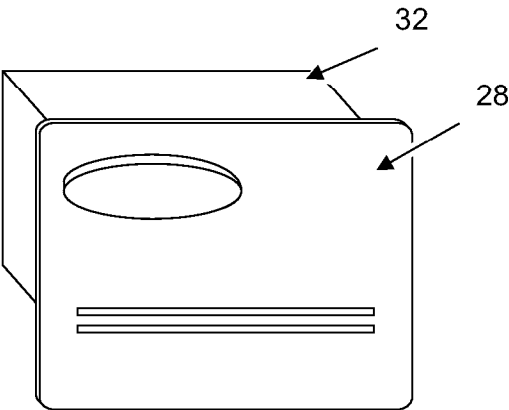


Fig. 4d

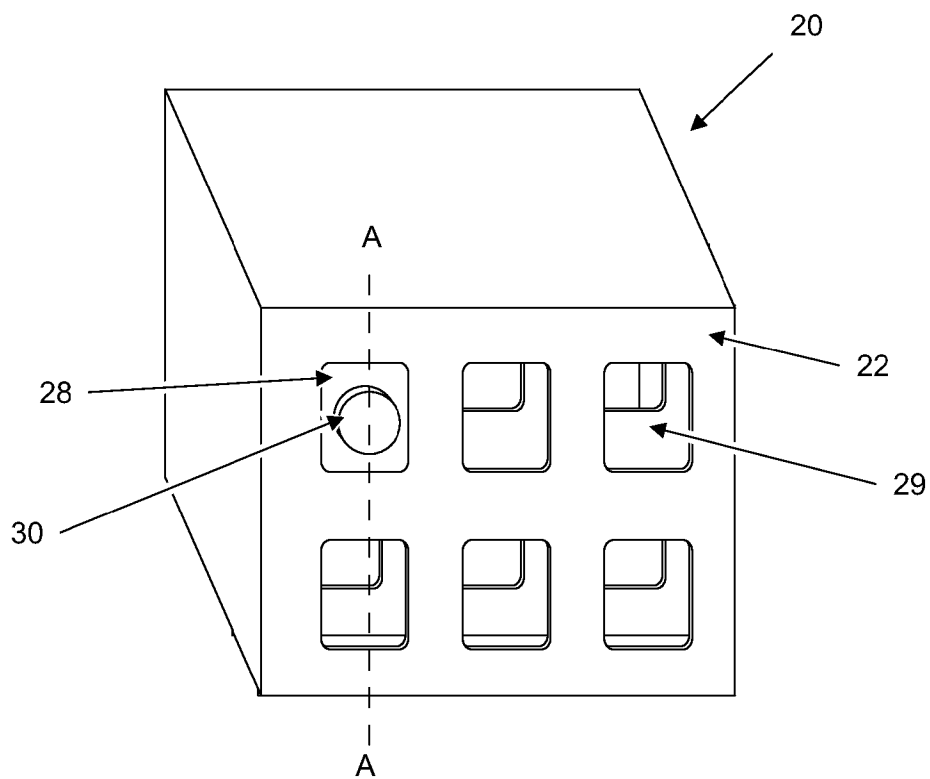


Fig. 5a

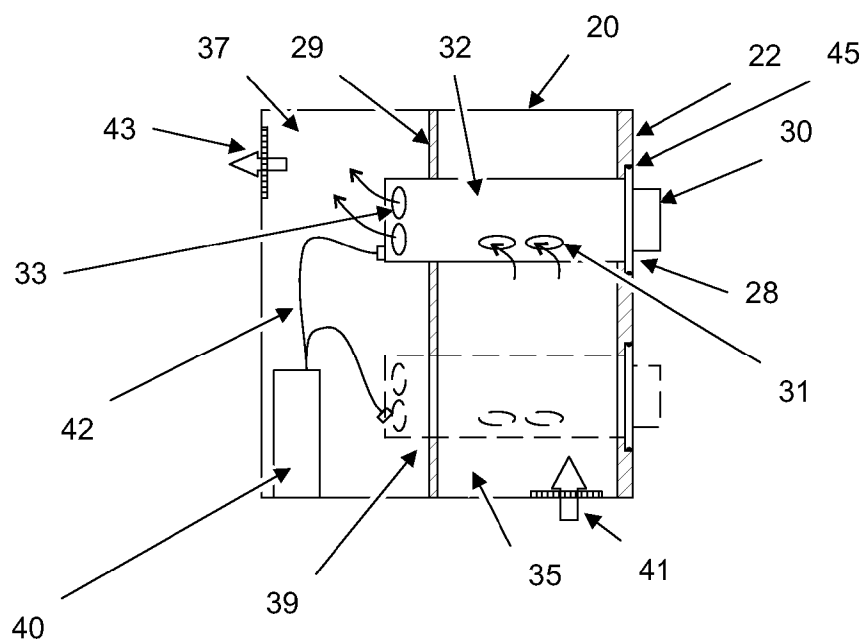


Fig. 5b

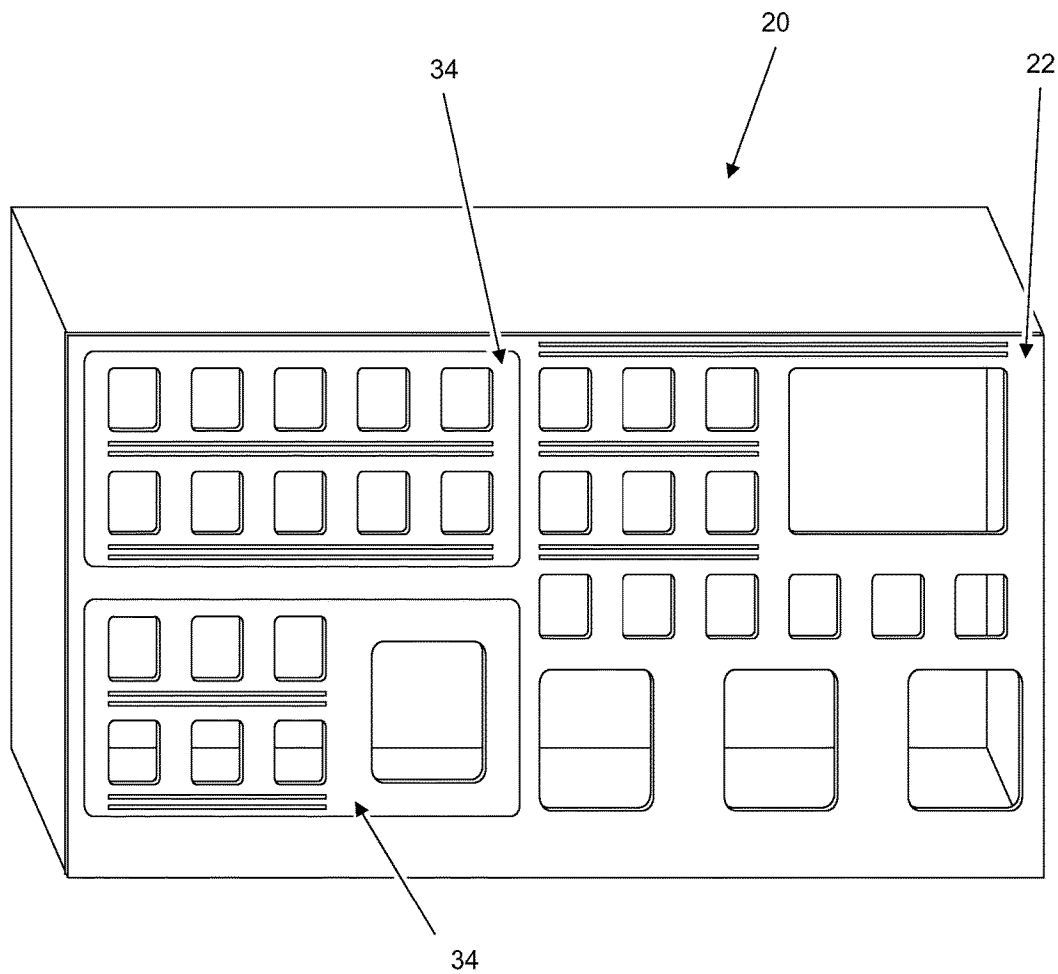


Fig. 6



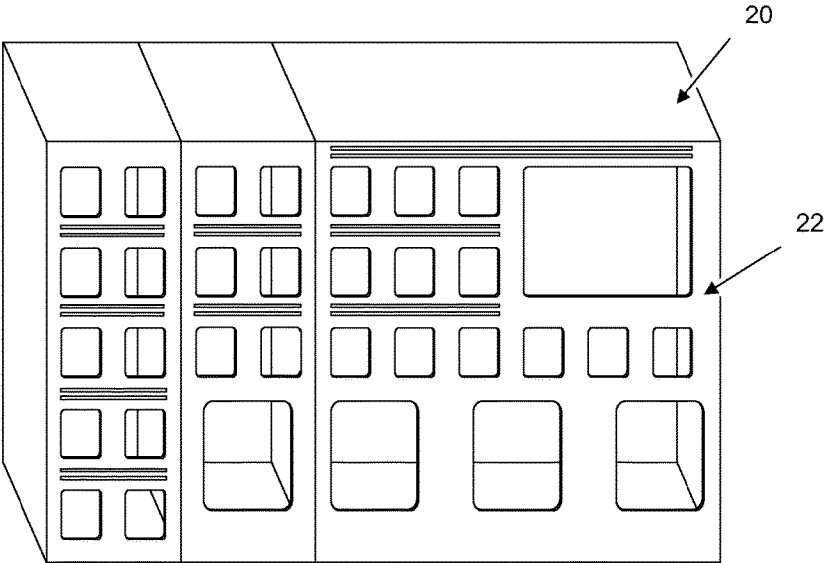


Fig. 7a

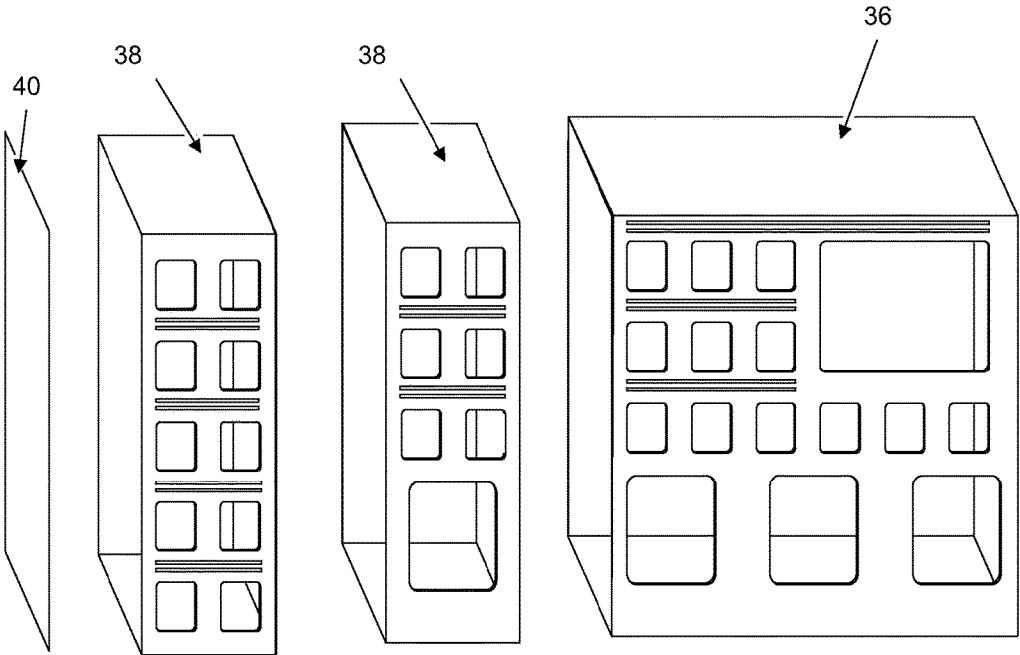
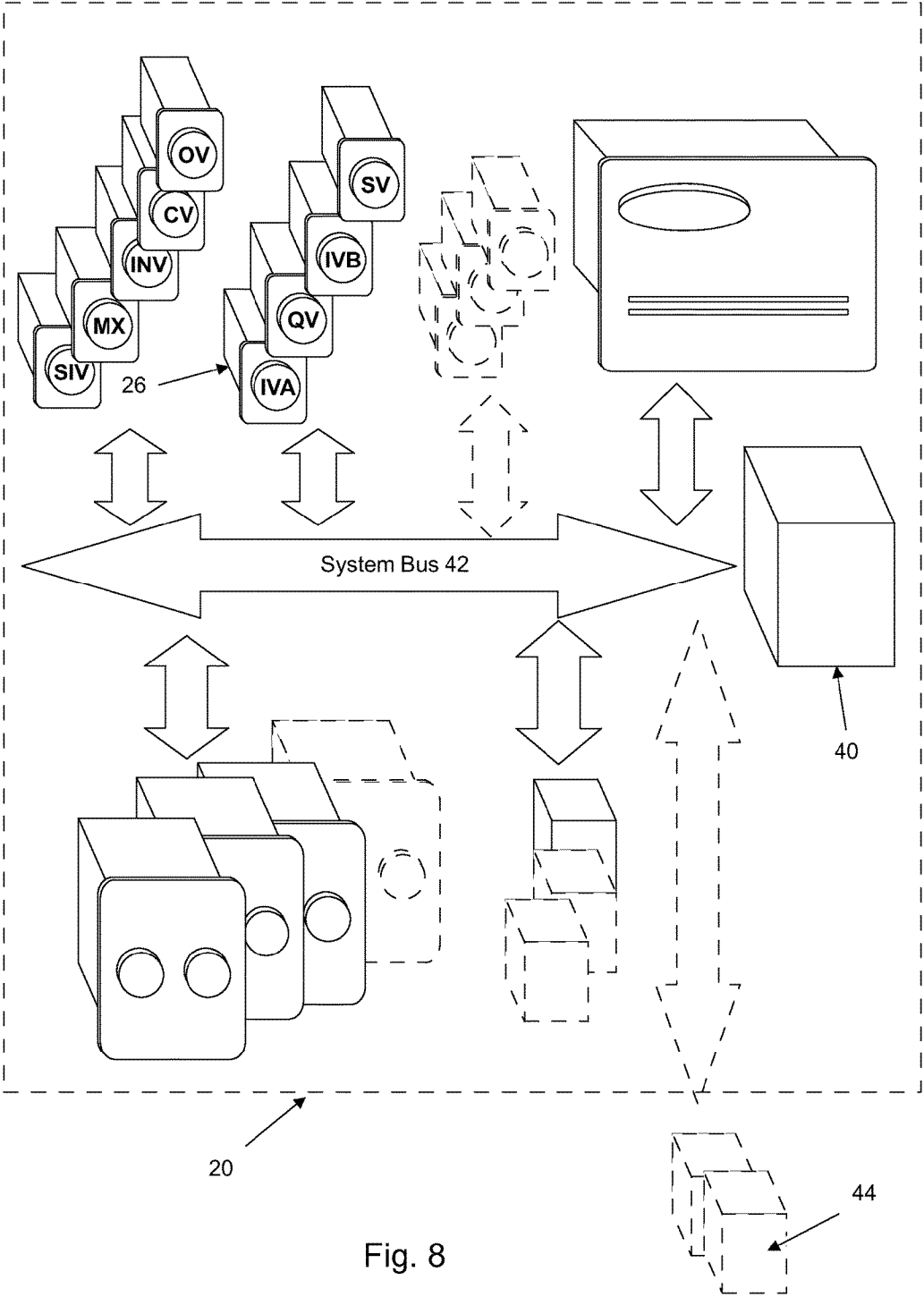


Fig. 7b



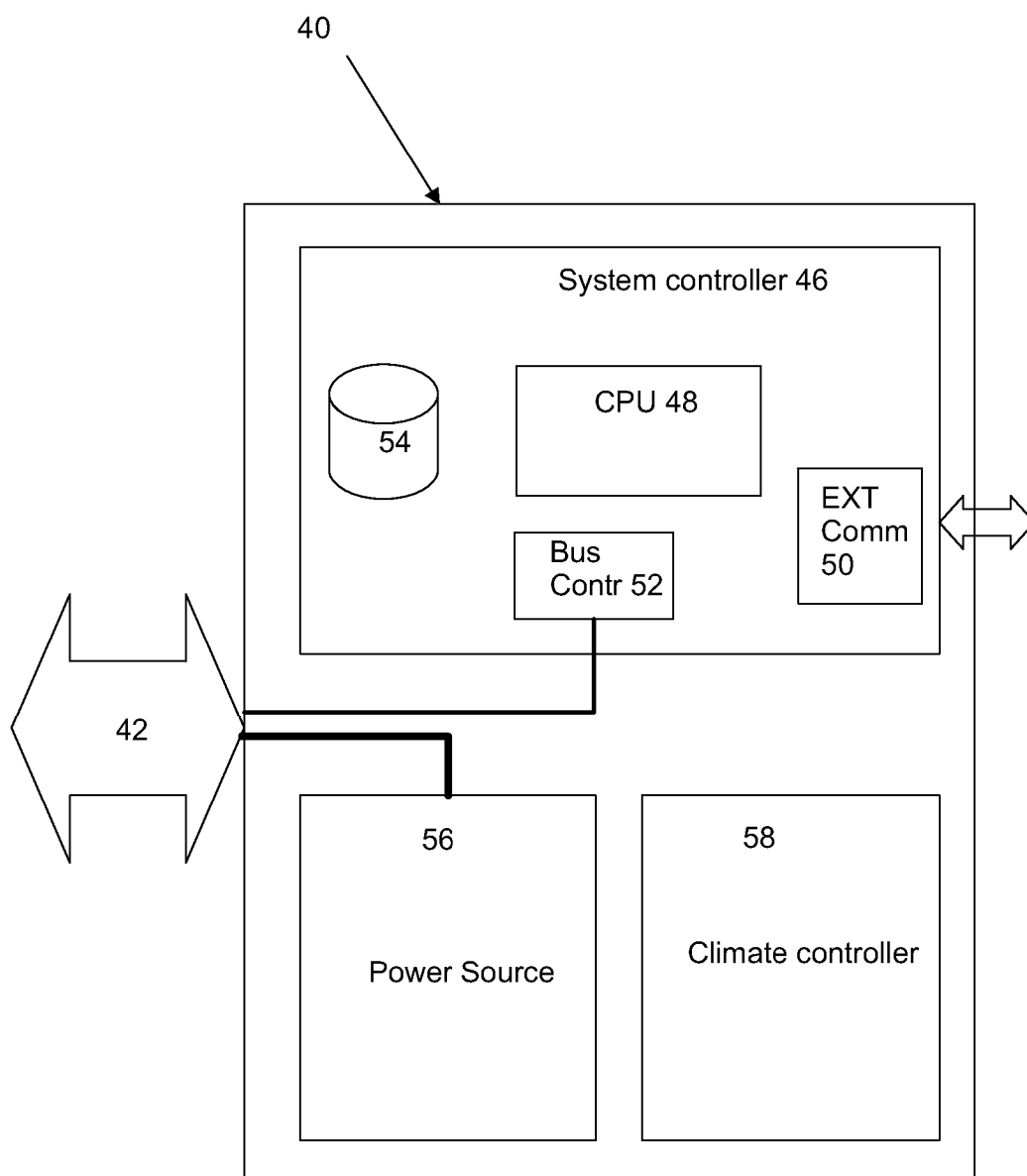


Fig. 9

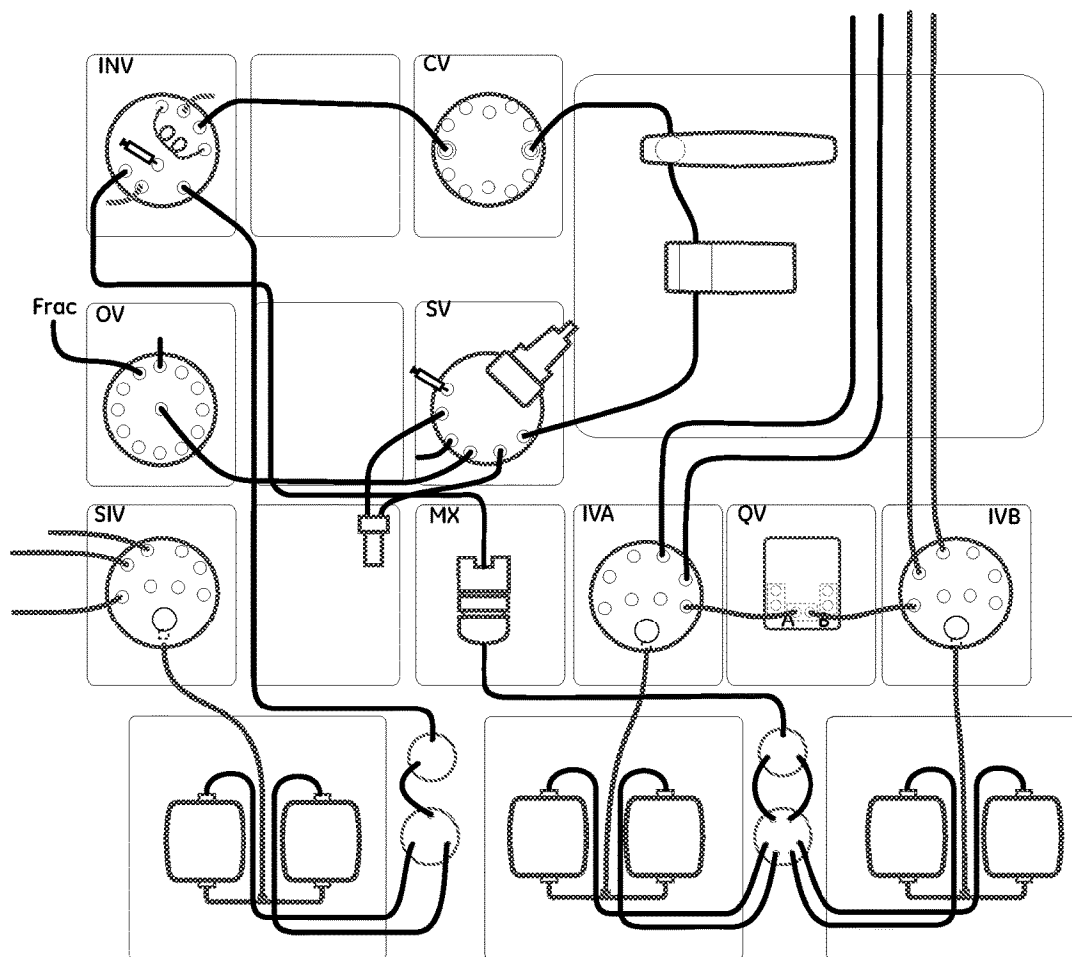


Fig. 10

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**AUTOMATED FLUID HANDLING SYSTEM****CROSS REFERENCE TO RELATED APPLICATION**

This application is a Continuation of U.S. patent application Ser. No. 15/165,876 filed May 26, 2016 which is a Continuation of U.S. patent application Ser. No. 14/463,039 filed Aug. 19, 2014 (now U.S. Pat. No. 9,404,902) which is a Continuation of U.S. patent application Ser. No. 13/376,929 (now U.S. Pat. No. 8,821,718) filed Dec. 8, 2011 which is a 35 U.S.C. §371 National Phase of International Patent Application No. PCT/SE2010/050624 filed Jun. 4, 2010 which claims priority to Swedish Patent Application No. 0950431-7 filed Jun. 9, 2009, the disclosure of these prior applications are hereby incorporated in their entirety by reference

**BACKGROUND OF THE INVENTION**

The present invention relates to the art of fluid handling system systems, and in particular to an automated fluid handling system that is highly flexible and configurable. The fluid handling system may e.g. be a liquid chromatography system, a filtration system, a chemical synthesis system or the like.

There is a large range of fluid handling systems e.g. in laboratories. Such systems comprise a number of fluid handling units, e.g. one or more pumps, valves, mixers, sensor units etc of different types. Said fluid handling units are interconnected by fluid conduits in the form of, rigid or flexible tubes or the like. Even though some systems may be designed for a specific type of application with a specific flow path, there often exists a need for flexibility and ability to alter or optimize the fluid flow path of the system. Moreover, upgrading is often restricted to specific kits provided by the manufacturer, and upgrade kits often is supplied as external add-on equipment to be arranged besides the original system, thus enlarging the foot print of the system and that need to be connected to the system both fluidically and electrically (i.e. to a system control bus or the like). Moreover, replacement of defect fluid handling units is a time consuming and delicate task.

One type of liquid handling system is liquid chromatography systems which is a standard method in laboratories, and there are a broad range of liquid chromatography systems available on the market. Common to most of the present systems is the lack of flexibility in adapting the instrument to a variety of different applications.

**SUMMARY OF THE INVENTION**

The object of the invention is to provide a new fluid handling system, which system overcomes one or more drawbacks of the prior art. This is achieved by the fluid handling system as defined in the independent claims.

One advantage with such a fluid handling systems is that the system may easily be upgraded without need for add-on equipment, and that the flow path may be easily optimized for new experimental setups.

Embodiments of the invention are defined in the dependent claims.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The invention will be described in detail below with reference to the drawings, in which

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FIG. 1 shows one embodiment of a fluid handling system in the form of a liquid chromatography system, according to the present invention.

FIG. 2 is a schematic illustration of a housing with a liquid handling panel of the fluid handling system of FIG. 1.

FIG. 3 is a schematic illustration of the housing with the liquid handling panel of FIG. 2 with the modular components of the fluid handling system removed.

FIGS. 4a to 4d are schematic illustrations of examples of component modules of the fluid handling system removed.

FIGS. 5a and 5b show a schematic embodiment of an automated fluid handling system.

FIG. 6 is a schematic illustration of an embodiment of a housing with a modular liquid handling panel with the modular components of the fluid handling system removed.

FIGS. 7a and 7b are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with the modular components of the fluid handling system removed.

FIG. 8 is a schematic illustration of an embodiment of the system architecture of one embodiment of a fluid handling system according to the present invention.

FIG. 9 is a schematic illustration of an embodiment of a master control unit of one embodiment of a fluid handling system according to the present invention.

FIG. 10 is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel for the liquid chromatography system of FIG. 1.

**DETAILED DESCRIPTION OF THE INVENTION**

According to one embodiment, there is provided an automated fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components with an external fluidics section and an internal non fluidics section, and wherein the housing comprises a liquid handling panel with two or more of component positions for receiving said interchangeable modular components such that the external fluidics section is separated from the non fluidics section by the liquid handling panel.

According to another embodiment, there is provided a fluid handling system in the form of a liquid chromatography system comprising a housing, two or more high pressure pumps, at least one sensor unit and a plurality of fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components and the housing comprises a liquid handling panel with a plurality of component positions for receiving said modular components.

FIG. 1 shows one embodiment of an automated fluid handling system modular in the form of a liquid chromatography system, with a plurality of interchangeable modular components arranged in a liquid handling panel wherein the reference numbers denotes:

1. Injection valve
2. Column valve with integrated pressure sensors
3. Conductivity monitor
4. UV monitor
5. Quaternary valve
6. Inlet valve B with integrated air sensor
7. System pump
8. Pressure monitor, system pump
9. Inlet valve A with integrated air sensor
10. System pump

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11. Pressure monitor, sample pump
12. Sample pump
13. Rinsing system
14. Mixer with online filter
15. Sample inlet valve with integrated air sensor
16. Flow restrictor
17. pH valve
18. Outlet valve

The disclosed embodiment is supplied with three high precision pumps 7, 10, 12. There are two System pumps 7, 10, System pump A 10 and System pump B 7, and one Sample pump 12. The System pumps 7, 10 may be used individually, or in combination to generate isocratic or gradient elution in purification methods. The Sample pump 12 is dedicated for direct loading of sample onto a column, or for filling of sample loops.

Function of the Pumps:

Each pump module consists of two pump heads (not shown). The individual heads are identical but actuated in opposite phase to each other by individual stepper motors, controlled by a microprocessor. The two pistons and pump heads work alternately to give a continuous, low pulsation, liquid delivery. The flow rate of the two System pumps may be varied between about 0.001 ml/min and 25.000 ml/min and the maximum operating pressure is about 20 MPa. The flow rate of the Sample pump may e.g. be varied between 0.01 and 25 ml/min and according to one embodiment the maximum operating pressure is 10 MPa.

According to one embodiment, the plurality of fluid control valves of at least two different configurations are valves of rotary type. Such a motorized rotary valve may consist of a Valve head with a number of defined bores with channels to the inlet and outlet ports of the valve. The Rotary disc, mounted on the motor, has a number of defined channels. The pattern of channels of the Rotary disc together with the pattern and location of the ports of the Valve head, define the flow path and function of each type of valve. When the Rotary disc turns, the flow path in the valve changes.

One embodiment of fluid control valves are Inlet valves A and B (9, 6 respectively) that are used to select which buffers or samples to use in a run, and Sample inlet valve 15 that is located before Sample pump 12. Inlet valve A 9 is located before System pump A 10, Inlet valve B 6 is located before System pump B 10, and Sample inlet valve 15 is located before Sample pump 12. Inlet valve A and Inlet valve B are connected to another embodiment of a fluid control valve in the form of a Quaternary valve 5. The Quaternary valve is used for automatic buffer preparation, and for formation of quaternary gradients. The number of inlets can be increased by installing component modules with extra inlet valves. Inlet valve A and Inlet valve B enable automatic changing between different buffers and wash solutions, and can be used to generate gradients by mixing buffer A and buffer B. The air sensors integrated in Inlet valve A and Inlet valve B can be used to prevent introduction of air into the pumps and columns.

The Quaternary valve is used for automatic mixing of four different solutions. The Quaternary valve opens one inlet port at a time, and the different solutions are mixed in a Mixer 14 to form the desired buffer. The opening time in the switching valve is controlled by the system. The volume for each inlet port opening increases stepwise when the flow increases. To obtain a homogeneous buffer composition, one has to make sure to use a mixer chamber volume suitable for the flow rate of the method.

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The Quaternary valve can be used to create a gradient using four different solutions simultaneously in any combination. The percentage of each solution is controlled by instructions in the method. It is possible to form gradients that changes the percentage of two, three or four solutions linearly over time. This is useful when advanced methods are developed.

The Sample inlet valve 15 enables automatic loading of different samples when using the Sample pump 12 to inject sample directly onto the column or to fill a sample loop. The Sample inlet valve has an inlet dedicated for buffer. This Buffer inlet is used in methods to fill the Sample pump with solution before sample is introduced. The Buffer inlet is also used to wash the Sample pump with buffer between runs. The air sensor integrated in the Sample inlet valve is e.g. used when sample is applied from a vessel onto a column by selecting Inject all sample using air sensor in the Sample application phase of a method. This function uses the Buffer inlet is used to finalize sample injection and to remove air from the Sample pump.

Still another embodiment of fluid control valve may be an Injection valve 1, which is used to direct sample onto the column. The valve enables usage of a number of different sample application techniques. A sample loop can be connected to the Injection valve and filled either automatically using the Sample pump or manually using a syringe. The sample can also be injected directly onto the column using the Sample pump.

Still another embodiment of fluid control valve may be a Column valve 2 that is used for connection of columns to the system, and to direct the flow onto the column. Up to five columns can be connected to the disclosed embodiment of said valve simultaneously. The valve also has a built-in bypass capillary that enables bypassing of connected columns.

The number of column positions can be increased by installing an extra Column valve. Both top and bottom of each column shall be connected to the Column valve. The top of the column shall be connected to one of the A ports (e.g., 1A), and the bottom of the column shall be connected to the corresponding B port (e.g., 1B). The flow direction can be set either from the top of the column to the bottom of the column, Down flow, or from the bottom of the column to the top of the column, Up flow. In the default flow path of the Column valve the columns are bypassed. Pressure monitors that measures the actual pressure over the column are integrated into the inlet and outlet ports of the Column valve.

Still another embodiment of fluid control valve may be a pH valve 17 that has an integrated flow cell where a pH electrode can be installed. This enables in-line monitoring of pH during the run. A flow restrictor is connected to the pH valve and can be included in the flow path to generate a backpressure high enough to prevent formation of air bubbles in the UV flow cell. The pH valve is used to direct the flow to the pH electrode and to the flow restrictor, or to bypass one or both.

Still another embodiment of fluid control valve may be an Outlet valve 18 that is used to direct the flow to a Fraction collector (not shown), to any of e.g. 10 outlet ports, or to waste. The number of outlets can be increased by installing an extra Outlet valve.

A Mixer 14 may e.g. be located after System pump A and System pump B and before the Injection valve. The purpose of the Mixer is to make sure that the buffers from the System

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pumps are mixed to give a homogenous buffer composition. The Mixer has a built-in filter that prevents impurities from entering the flow path.

To fulfill a desired purpose, with the disclosed liquid chromatography system it is possible to adapt and extend the flow path in a simple and a flexible way. Up to three extra fluid control valves or the like can be installed using the free valve positions. Dummy modules are installed in these positions at delivery. To obtain an optional flow path, it is also possible to move the standard fluid control valves to other positions. There are also two types of extra air sensors available which can be installed before Sample inlet valve or after Injection valve.

In the configuration disclosed in FIG. 1, 7 inlets are available for each inlet valve. To increase the number of inlets, an extra inlet valve can be installed which increases the number of inlets to 14 for one of the valves. This optional configuration can be convenient for example when a larger number of samples will be used. There is also a general type of inlet valve, Valve X, which can be used to increase the number of inlets to for example the Quaternary valve.

In the configuration disclosed in FIG. 1 with one column valve, 5 column positions are available. To increase the number of column positions to 10, an additional column valve can be installed in the instrument. An application can be to evaluate a number of different columns in method optimization.

In the configuration disclosed in FIG. 1 with one outlet valve, 10 outlet positions are available. To increase the number of outlets, one or two extra outlet valves can be connected, adding up to a total of 21 or 32 outlet positions. This optional configuration is convenient when collecting a number of large fractions outside the fraction collector.

Optional modules are easy to install in the disclosed modular liquid chromatography system. The dummy module is removed with a hexagon wrench and a bus cable is disconnected. The bus cable is connected to the optional fluid control valve or the like which is assembled in the instrument. The module is then added to the System properties in the control software. The available optional modules may e.g. be pre-configured to give the desired function. However, the function of a valve may e.g. be changed by changing the Node ID.

FIG. 2 is a schematic illustration of a housing 20 with a liquid handling panel 22 of the fluid handling system in the form of a modular liquid chromatography system 100 of FIG. 1. In FIG. 2 some components have been removed for clarity reasons. In the disclosed configuration, as disclosed in detail above, the modular liquid chromatography system 100 comprises a plurality of fluid control valves in the form of: Injection valve 1, Column valve 2, Quaternary valve 5, Inlet valve B 6, Inlet valve A 9, Sample inlet valve 15, pH valve 17, and Outlet valve 18. The chromatography system 100 further comprises UV monitor 4, System pump B 7, System pump A 10, Sample pump 12, Mixer 14, and three Dummy modules 24. According to one embodiment, all liquid handling components and sensors arranged at the liquid handling panel 22 are designed to be readily interchangeable. The interchangeability provides improved service and upgrade possibilities and also a possibility to customize the positions of the respective liquid handling components, such as the fluid control valves, e.g. in order to optimize the fluid path for a specific experimental setup. As is illustrated in FIG. 2, there are three large component positions e.g. for pump modules, one UV-sensor position and 9 standard component positions, e.g. for fluid control valves or the like. The component positions are given a

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standardized size and shape to provide simple interchangeability. According to one embodiment, each modular component is retained in a mating component position by a single screw, and it is connected to the master control unit by a single bus cable providing both communication and system power to each component. FIG. 3 is a schematic illustration of the housing with the liquid handling panel of FIG. 2 with the modular components of the liquid chromatography system removed.

FIGS. 4a to 4d are schematic illustrations of examples of fluid handling units in the form of modular component of the fluid handling system removed. FIG. 4a shows a standard interchangeable modular component 26, e.g. a fluid control valve or the like. The standard component module 26 comprises a panel member 28, an external fluidics section 30 and an internal non-fluidics section 32. According to one embodiment, the panel member 28 essentially separates the fluidics in the external fluidics section 30 from electronics and control means in the internal non-fluidics section 32.

FIG. 4b shows a Dummy module 24, which is intended to be placed in non used standard component positions. In the disclosed embodiment, the Dummy modules are provided with mounting grooves for attachment of accessories to the system. In the disclosed embodiment the dummy module is shown as a panel member 28 without any internal section. FIGS. 4c and 4d shows a pump module and an UV-module, respectively, each having an external fluidics section 30 and an internal non-fluidics section 32.

As is disclosed in FIGS. 4a to 4d, the interchangeable modular components 26 comprises a panel member arranged to separate the fluidics section from the non fluidics section and for attachment to a component position in the liquid handling panel. Said panel attachment member may be arranged so that all fluid connections of said modular component are arranged on a wet side of the panel attachment member separating them from electrical components that are arranged on a dry side thereof, hence providing a high degree of liquid resistance at the external part of the fluid handling panel, and so that the liquid resistance requirements for the internal sections may be somewhat lightened. According to one embodiment, the interchangeable modular components are sealed against the liquid handling panel by a sealing member. According to another embodiment, not shown, the modular component does not comprise any panel member, but there is provided a suitable sealing arrangement between the component position openings of the liquid handling panel and the external surface of the interchangeable modular components 26. In the disclosed embodiments, the component position openings of the liquid handling panel and the interchangeable modular components 26 are shown to have an essentially rectangular crosssectional shape, but other shapes may be equally applicable. According to one embodiment, there is provided a general fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components as is schematically disclosed in FIG. 5a. As discussed above such a system may be configured for essentially any type of automated liquid handling operations provided that suitable fluid handling units are provided as interchangeable modular components for the system. According to one embodiment there is provided an automated fluid handling system comprising at least one fluid pump, at least one sensor unit and two or more fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components.



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The liquid handling panel **22** of the fluid handling system may e.g. be designed in any suitable manner to allow the modular components to be arranged in an efficient manner.

FIGS. **5a** and **5b** shows a schematic embodiment of an automated fluid handling system wherein the housing **20** comprises an internal climate panel **29** arranged at a distance behind the liquid handling panel **22** defining an air inlet compartment **35** and air outlet compartment **37** in the housing **20**, the climate panel **29** being provided with complementary component positions **39** for receiving the internal non fluidics section **32** of the interchangeable modular components **26**, and wherein the non-fluidics section **32** of at least one interchangeable modular component is provided with one or more air inlet openings **31** located in the air inlet compartment **35** and one or more air outlet openings **33** located in the air outlet compartment **37** when the interchangeable modular component arranged in position in the component position. FIG. **5b** shows the fluid handling system of FIG. **5a** in a schematic cross sectional view. As is indicated by inlet vent **41** and outlet vent **43**, air for cooling interchangeable modular components **26** provided with air inlet and outlet openings **31**, **33** is preferably arranged to enter the air inlet compartment **35** at a distance from the outlet vent **43** in order to avoid recirculation of air. The air circulation in the system may be achieved by a system cooling unit (not shown) providing a flow of air from the air inlet compartment **35** to the air outlet compartment **37**, through the at least one interchangeable modular component **26**. Alternatively, the at least one interchangeable modular component **26** is provided with a local cooling unit (not shown) providing a flow of air from the air inlet compartment **35** to the air outlet compartment **37**. As is indicated, the complementary component positions **39** are arranged to provide a relatively air flow tight fit with respect to the internal non fluidics section **32** of the interchangeable modular components **26**, and according to one embodiment, this may be achieved by a sealing arrangement. In FIG. **5b**, there is shown a sealing member **45** for sealing the interchangeable modular components **26** with respect to the liquid handling panel **22**, as discussed above. Other sealing member arrangements may be envisaged by a person skilled in the art. According to one embodiment, fluids are strictly restricted to the fluidics section **30** of the interchangeable modular component **26**, but in alternative embodiments, only fluid connections are restricted to the fluidics section **30** allowing fluid to "cross" the fluid handling panel inside the non-fluidics section **30** of the interchangeable modular component **26**.

In FIG. **5b** there is further shown a master control unit **40** and buss connectors **42** for connecting the interchangeable modular components **26** to the master control unit **40**. According to one embodiment, the component positions including the buss connectors **42** and the interchangeable modular components **26** are of plug and play configuration with respect to each other.

FIG. **6** is a schematic illustration of an embodiment of a housing **20** with a modular liquid handling panel **22** with the modular components of the liquid chromatography system removed. In the disclosed embodiment, also the layout of the liquid handling panel **22** is configurable by means of two interchangeable panel sections **34** which may be selected in accordance with the desired layout of the system. In FIG. **6** two different layouts of the interchangeable panel sections are disclosed, but the layout may include any suitable configuration.

FIGS. **7a** and **7b** are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with

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the modular components of the liquid chromatography system removed. In the disclosed embodiment, the modular housing is comprised of a main housing **36** that comprises the master control unit including power supply and climate control for the whole housing, two expansion housing modules **38** and a side member **40**. This approach provides very flexible expansion possibilities for the chromatography system, while preserving the benefits of a single master control unit including power supply and climate control.

FIG. **8** is a schematic illustration of an embodiment of the system architecture of one embodiment of a modular liquid chromatography system according to the present invention. As mentioned above, the chromatography system may comprise a master control unit **40** arranged to communicate with all modular components e.g. **1-26**, over a system bus **42** such as a CAN-bus or the like. In one embodiment, each modular component is provided with a dedicated CPU unit allowing the component to independently perform operations in response to instructions over the BUS **42**. In order to minimize the number of connectors to be attached to each modular component, the bus **42** further comprises power feed for the modular components. The Bus **42** may be connected to any suitable number of modular components arranged in the housing **20**, but also to one or more modular components **44** outside of the housing **20** or the like. As is mentioned briefly above, the master control unit may further be arranged to control the climate in the housing. In addition to the disclosed modular components, other components of the chromatography system, e.g. a fraction collector or the like, may be arranged in the housing and the controlled climate therein.

According to one embodiment, different component modules are automatically identified by the master control unit, whereby they may be moved essentially freely between different positions. Moreover, the master control unit may be arranged to provide said information to Chromatography control software whereby experimental setup and planning may be performed. In one embodiment, the control system may be arranged to provide an optimized layout of the component modules with respect to the present layout of the liquid handling panel and available component modules for a specific experimental setup.

According to one embodiment, the interchangeable panel sections **34** of FIG. **5** and the expansion housing modules **38** of FIGS. **6a** and **6b** may be provided with means for automatic detection of the same to allow automatic configuration of the system by the master control unit **40**. In one embodiment, each interchangeable panel section **34** and expansion housing module **38** comprises a hub (not shown) for connection to the system bus **42** in order to expand the system bus **42** network to the number of component modules in each interchangeable panel section **34** or expansion housing module **38**.

FIG. **9** is a schematic illustration of an embodiment of a master control unit of one embodiment of a modular liquid chromatography system according to the present invention. The master control unit **40** comprises a system controller **46** for communicating with internal and external components and control computers (not shown) etc. According to one embodiment, the system controller comprises a suitable CPU **48**, a bus controller **52**, an external communications controller **50**, such as a LAN unit, and a storage device **54**. The bus controller **52** is providing communication with the component modules. The master control unit may further comprise a Power supply **56** and a climate controller **58** arranged to keep the internal climate in the housing **20** at a predetermined level as discussed above.



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FIG. 10 is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel. Taking into account the complexity of the disclosed interconnection arrangement, the benefit of optimizing the fluid paths in alternative configurations of the system becomes evident. The task of optimizing the fluid paths may e.g. be performed to reduce the total length/volume of the fluid paths/tubing arranged to interconnect the different component modules in the system. Alternatively the optimization may be performed to minimize the length/volume of one or more specific fluid paths, such as the sample output path from the column to the fraction collector, in order to minimize dispersion of the fractionized sample.

The invention claimed is:

1. An automated liquid chromatography system comprising:

a housing;

a master control unit connected to a system bus; and

three or more fluid handling units arranged as interchangeable modular components comprising (i) an external fluidics section, (ii) an internal non-fluidics section including a bus connector for directly connecting the interchangeable modular component with the system bus, and (iii) a panel member arranged to separate the fluidics section from the non-fluidics section;

wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing;

wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus;

wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus;

wherein the master control unit is arranged to automatically identify interchangeable modular components;

wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least three of the pump, the sensor unit, and the fluid control valves are interchangeable modular components; and

wherein the system is capable of performing automated liquid chromatography.

2. The chromatography system of claim 1, wherein the interchangeable modular components are sealed against the liquid handling panel by a sealing member.

3. The chromatography system of claim 1, wherein the interchangeable modular components are all of the same size.

4. The chromatography system of claim 1, wherein the interchangeable modular components are of two or more sizes.

5. The chromatography system of claim 1, wherein the liquid chromatography system further comprises a pH electrode that is external to the housing.

6. The chromatography system according to claim 5, wherein the at least two fluid control valves include an

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injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve.

7. The chromatography system according to claim 5, wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component.

8. The chromatography system according to claim 7, wherein the pH valve includes an integrated flow cell for in-line monitoring of pH levels.

9. The chromatography system of claim 1, wherein the liquid chromatography system further comprises at least one expansion housing module arranged to be attached to the housing and for accommodating additional interchangeable modular components.

10. The chromatography system of claim 1, wherein the liquid chromatography system comprises two double piston pumps, one injection valve for injecting sample onto a column connecting a flow path of the liquid chromatography system, a UV monitor, and a mixer, wherein the pumps, valve, monitor, and mixer are interchangeable modular components.

11. The chromatography system of claim 10, wherein the liquid chromatography system further comprises a column valve comprising pressure sensors integrated into inlet and outlet ports of the column valve for measuring the actual pressure over the connected column.

12. The chromatography system of claim 10, wherein the liquid chromatography system further comprises a sample inlet valve.

13. The chromatography system of claim 10, wherein the liquid chromatography system further comprises a conductivity monitor.

14. The chromatography system of claim 10, wherein the liquid chromatography system further comprises at least one expansion housing module arranged to be attached to the housing and for accommodating additional interchangeable modular components.

15. The chromatography system according to claim 1, wherein the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve.

16. The chromatography system of claim 1, wherein the liquid chromatography system includes two double piston pumps, one injection valve for injecting a sample onto a column connected to a flow path of the liquid chromatography system, a UV monitor, a mixer, a pH-valve with an integrated flow cell for in-line monitoring of pH levels, and a quaternary valve for automatic buffer preparation and formation of quaternary gradients, wherein the pumps, injection valve, monitor, mixer, pH valve, and quaternary valve are interchangeable modular components.

17. An automated liquid chromatography system comprising:

a housing;

a master control unit connected to a system bus; and

two or more fluid handling units arranged as interchangeable modular components comprising a panel member arranged to separate a fluidics section from a non-fluidics section, wherein the fluidics section of each interchangeable modular component comprises one or more fluid connectors for connecting the fluid handling unit to a liquid chromatography fluid path and wherein all fluid connectors are on an external side of the panel member, said liquid chromatography fluid path being reconfigurable by moving the interchangeable modular components freely between the component receiving

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positions, and wherein the non-fluidics section includes a bus connector for directly connecting the interchangeable modular components to the system bus;

wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing;

wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus;

wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus;

wherein the master control unit is arranged to automatically identify interchangeable modular components;

wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components; and

wherein the system is capable of performing automated liquid chromatography.

18. The chromatography system of claim 17, wherein the interchangeable modular components are all of the same size.

19. The chromatography system of claim 17, wherein the interchangeable modular components are of two or more sizes.

20. The chromatography system of claim 17, wherein the two or more component receiving positions are arranged in a two dimensional array.

21. The chromatography system of claim 17, wherein the housing comprises at least four component receiving positions.

22. The chromatography system of claim 17, wherein the liquid chromatograph system further comprises a pH electrode that is external to the housing.

23. The chromatography system according to claim 22, wherein the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve.

24. The chromatography system according to claim 22, wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component.

25. The chromatography system according to claim 24, wherein the pH valve includes an integrated flow cell for in-line monitoring of pH levels.

26. The chromatography system of claim 17, wherein the liquid chromatography system further comprises at least one expansion housing module arranged to be attached to the housing and for accommodating additional interchangeable modular components.

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27. An automated liquid chromatography system comprising:

a housing;

a master control unit connected to a system bus; and

two or more fluid handling units arranged as interchangeable modular components comprising a panel member arranged to separate a fluidics section from a non-fluidics section, wherein the fluidics section of each interchangeable modular component comprises one or more fluid connectors for connecting the fluid handling unit to a liquid chromatography fluid path and wherein all fluid connectors are on an external side of the panel member, said liquid chromatography fluid path being reconfigurable by moving the interchangeable modular components freely between the component receiving positions, and wherein the non-fluidics section includes a bus connector for directly connecting the interchangeable modular components to the system bus;

wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing;

wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus;

wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus;

wherein the master control unit is arranged to automatically identify interchangeable modular components;

wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components; and

wherein the system is capable of performing automated liquid chromatography.

28. The chromatography system of claim 27, wherein the interchangeable modular components are all of the same size; or of two or more sizes.

29. The chromatography system of claim 27, wherein the system further comprises at least one expansion housing module arranged to be attached to the housing and for accommodating additional interchangeable modular components.

30. The chromatography system of claim 27, wherein the system further comprises a pH electrode that is external to the housing, and wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component.

\* \* \* \* \*

# EXHIBIT 36



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(54) **AUTOMATED FLUID HANDLING SYSTEM**

(71) Applicant: **GE Healthcare Bio-Sciences AB**,  
 Uppsala (SE)

(72) Inventors: **Johan Blomberg**, Uppsala (SE); **Mats Lundkvist**, Uppsala (SE)

(73) Assignee: **GE Healthcare Bio-Science AB**,  
 Uppsala (SE)

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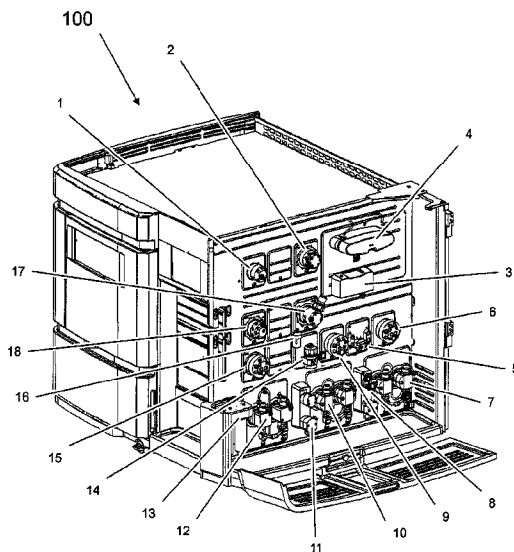
*Primary Examiner* — Ling X Xu

(74) *Attorney, Agent, or Firm* — Arent Fox LLP

(57) **ABSTRACT**

Automated fluid handling system comprising a housing (20) and two or more fluid handling units (26) arranged as interchangeable modular components with an external fluidics section (30) and an internal non fluidics section (32), and wherein the housing (20) comprises a liquid handling panel (22) with two or more of component positions for receiving said interchangeable modular components (26) such that the external fluidics section (30) is separated from the non fluidics section (32) by the liquid handling panel (22).

**29 Claims, 10 Drawing Sheets**



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**EX 122**

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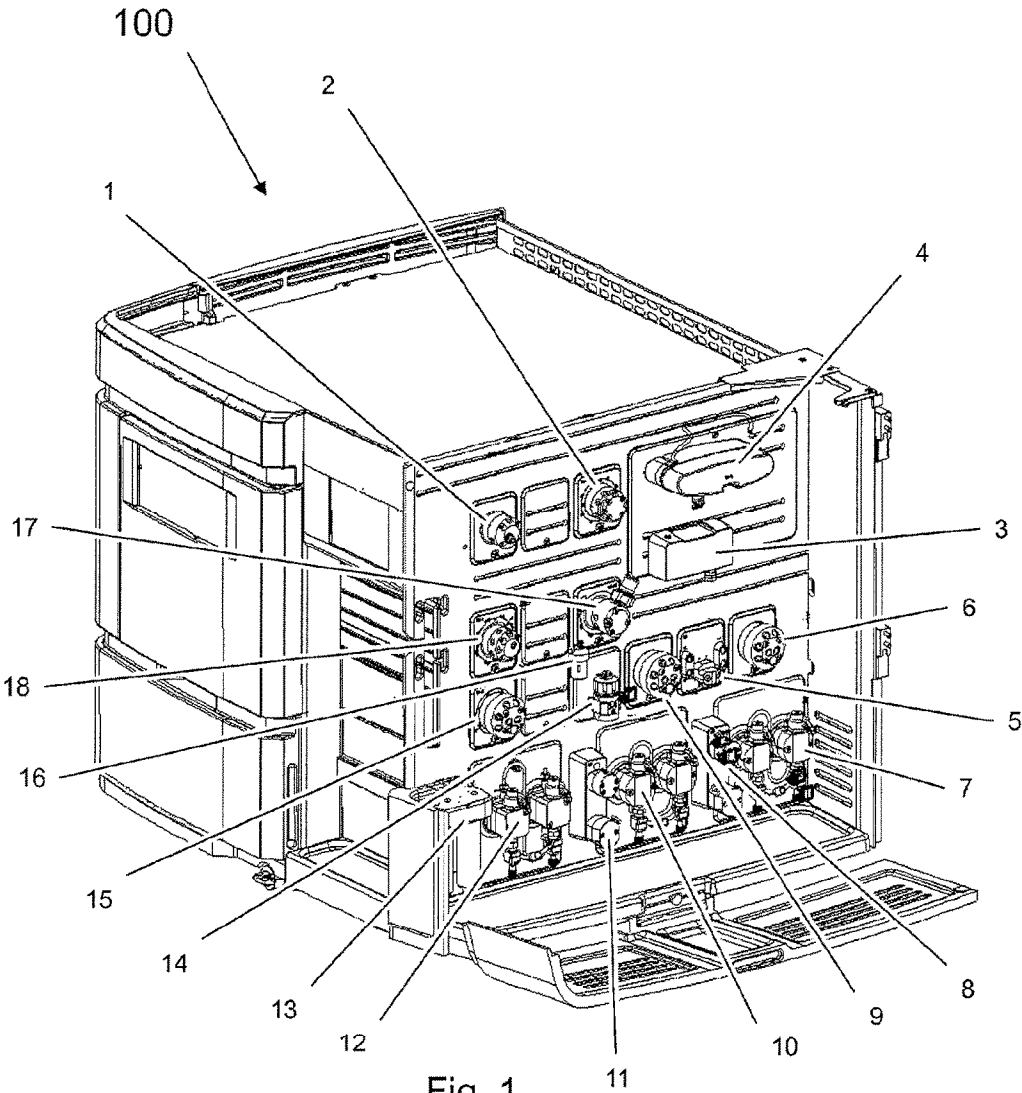


Fig. 1

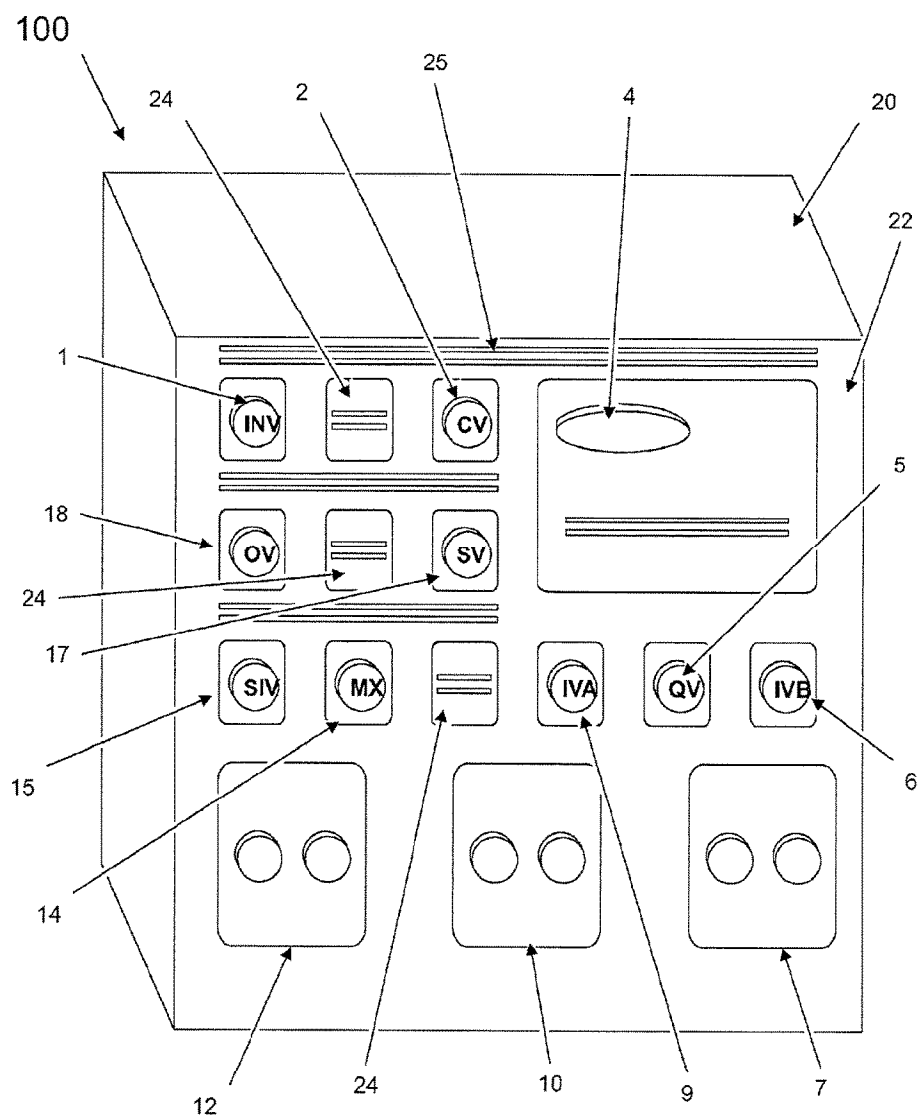


Fig. 2

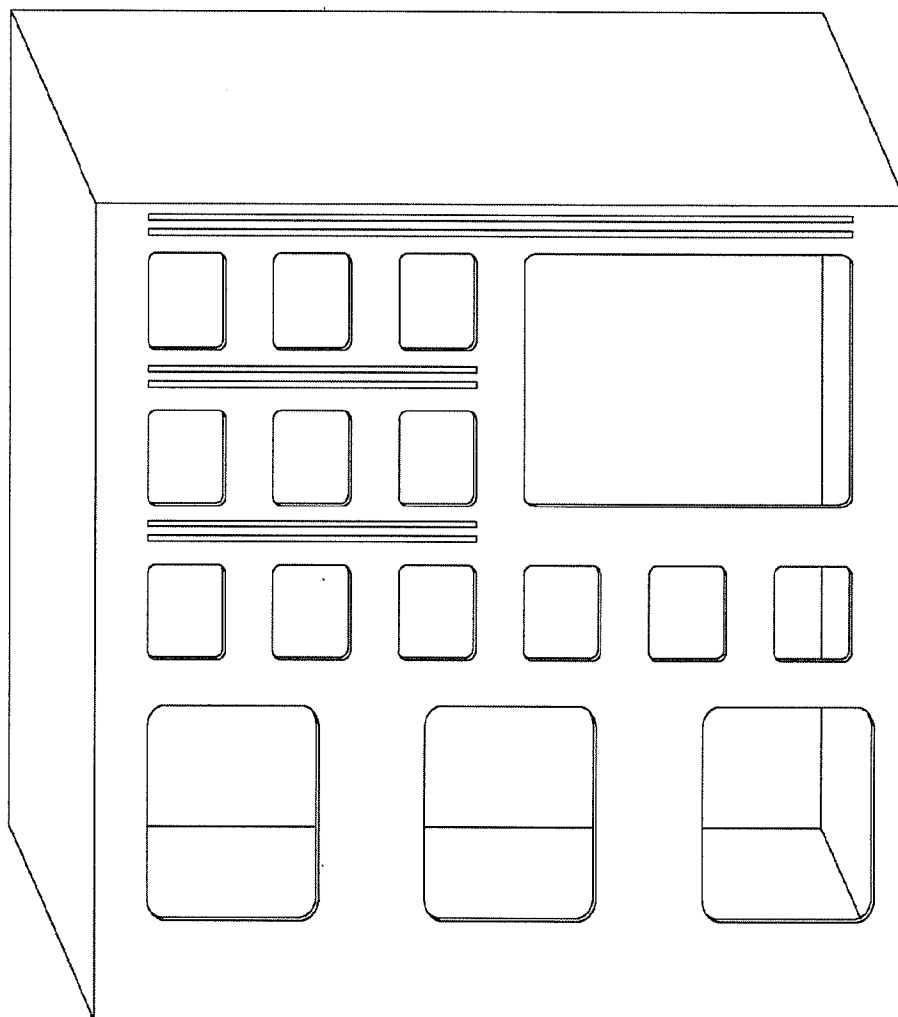


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**Fig. 3**

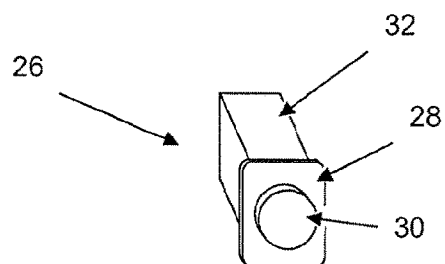


Fig. 4a

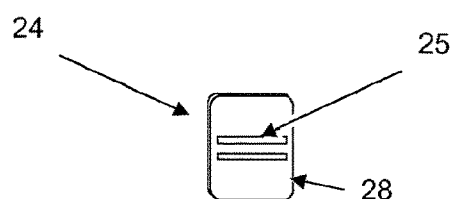


Fig. 4b

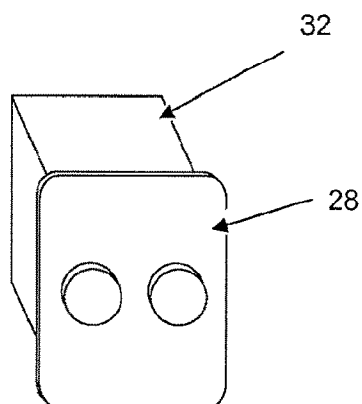


Fig. 4c

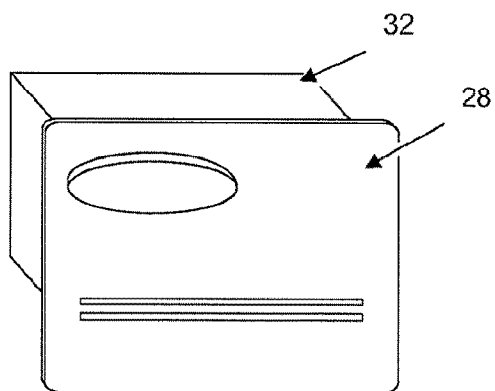


Fig. 4d

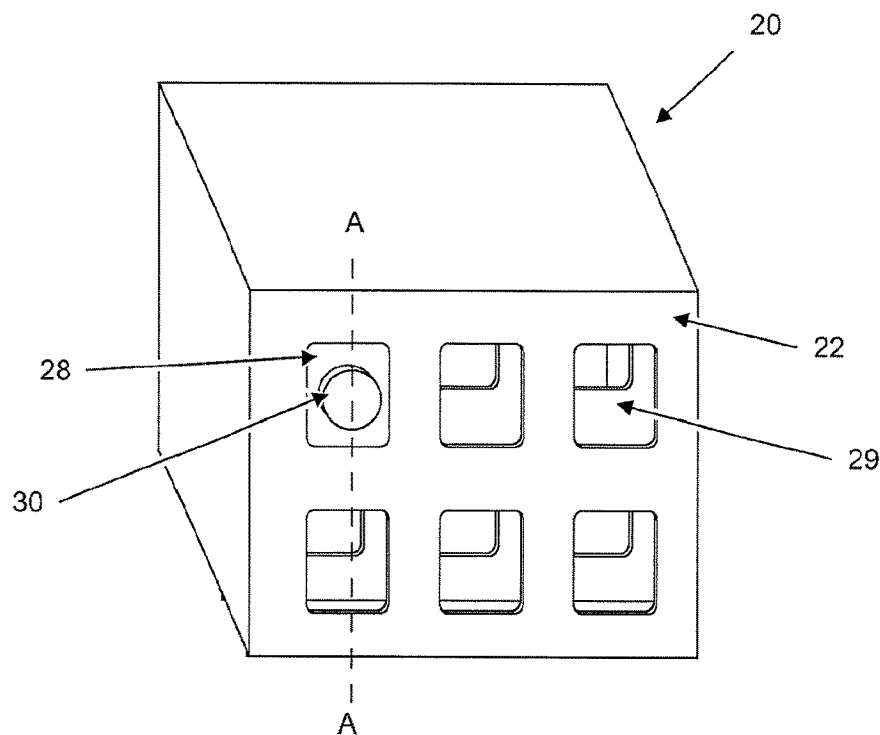


Fig. 5a

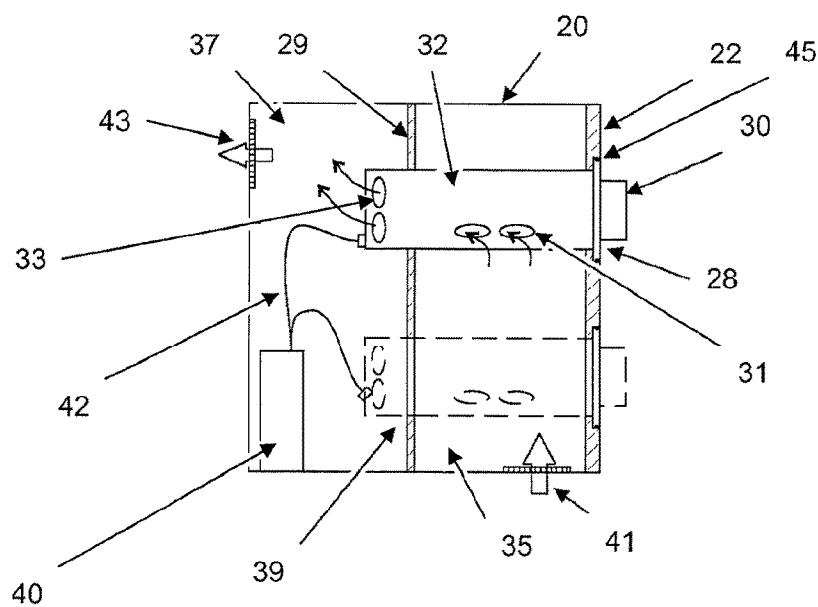


Fig. 5b

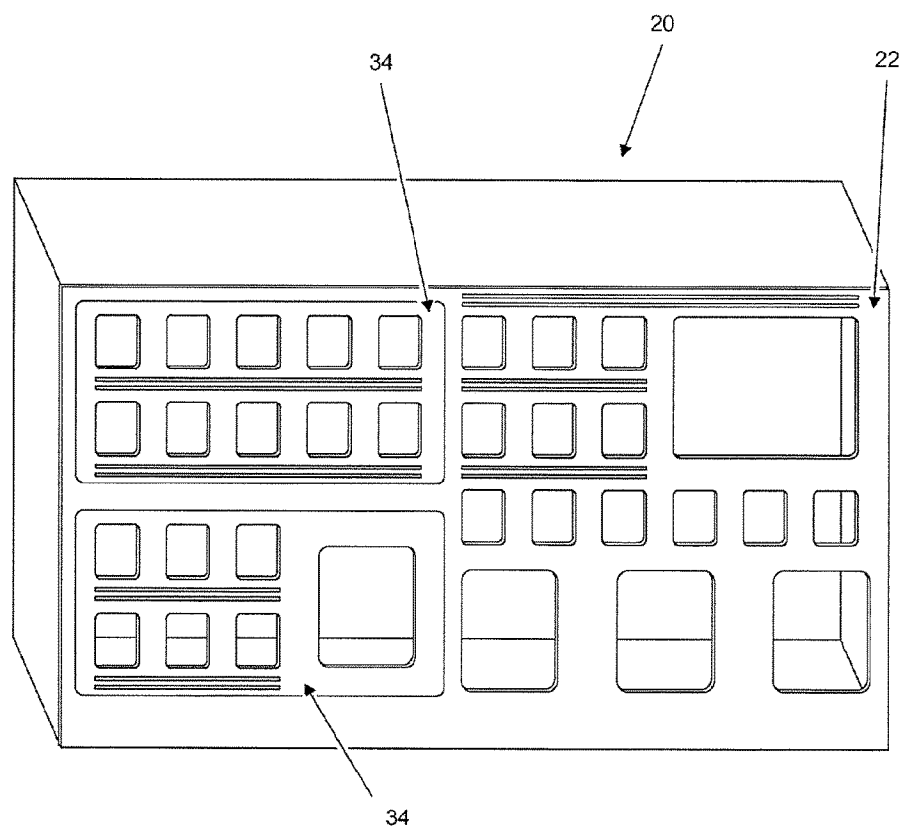


Fig. 6

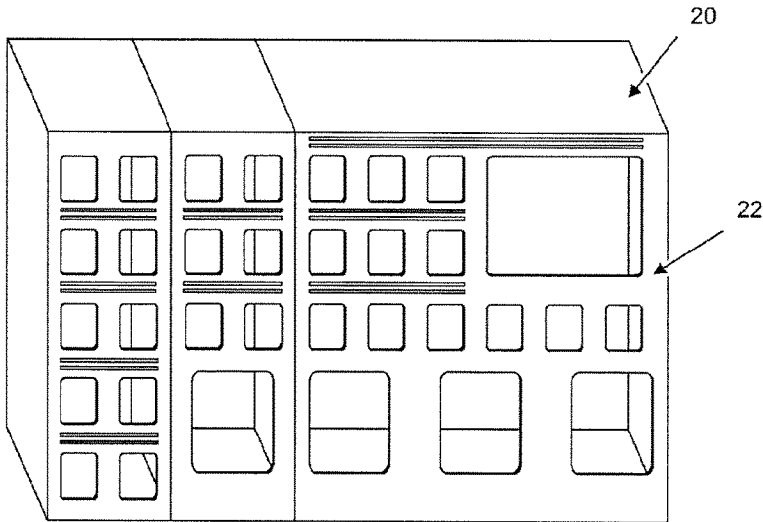


Fig. 7a

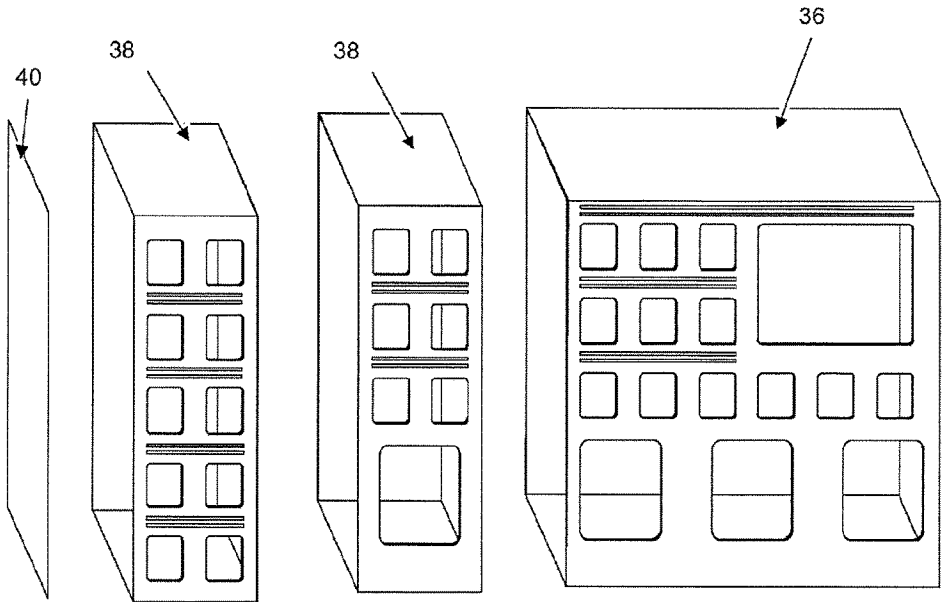


Fig. 7b

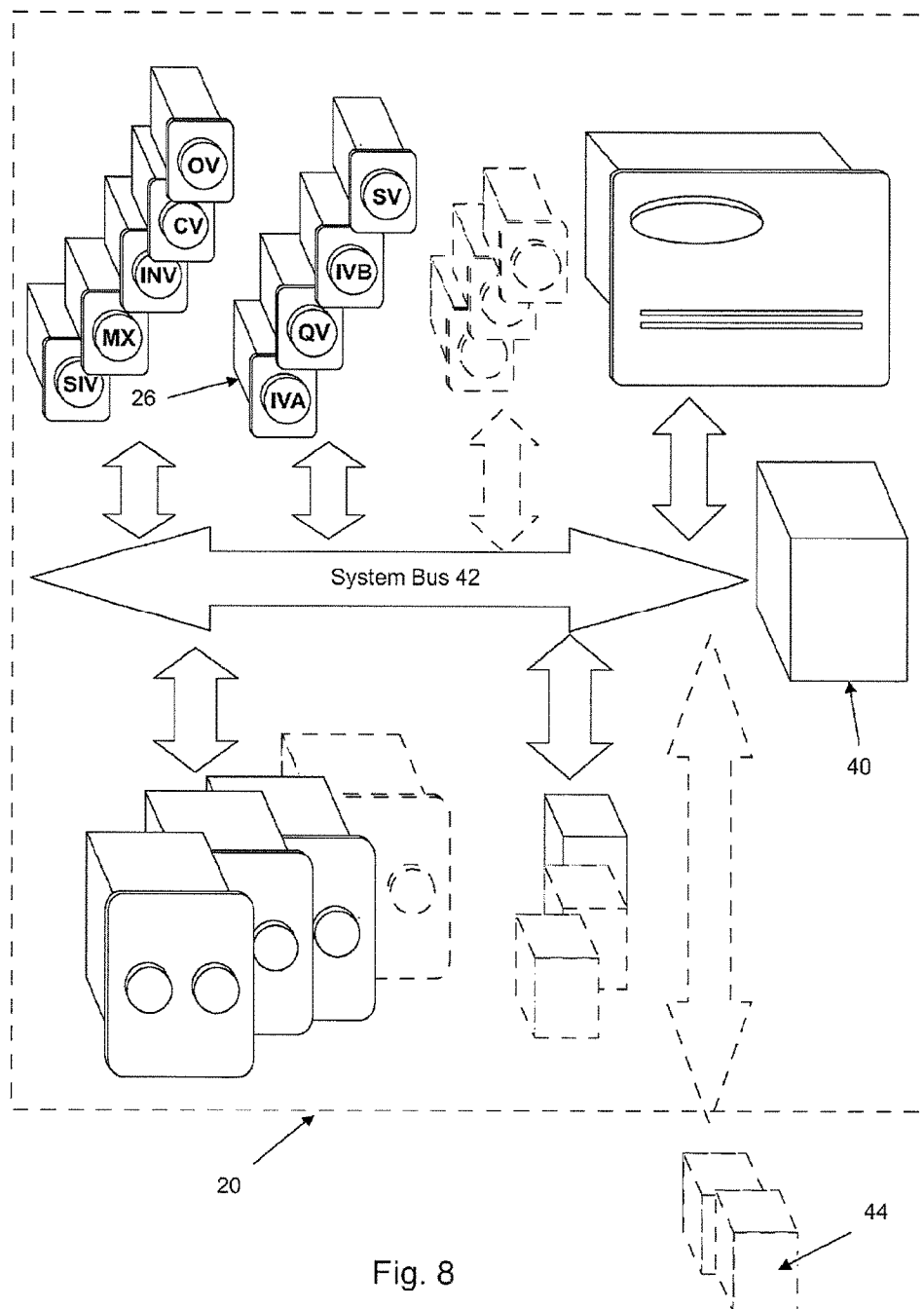


Fig. 8

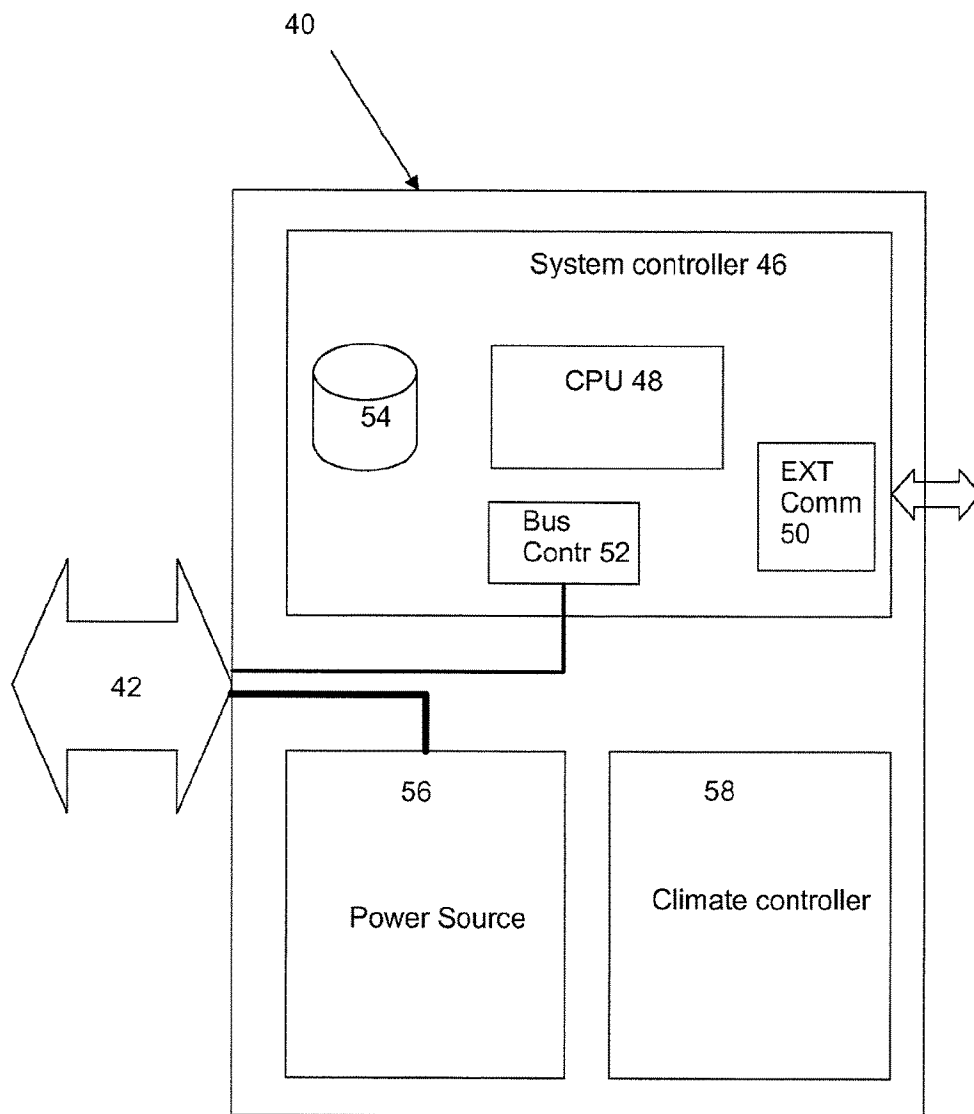


Fig. 9

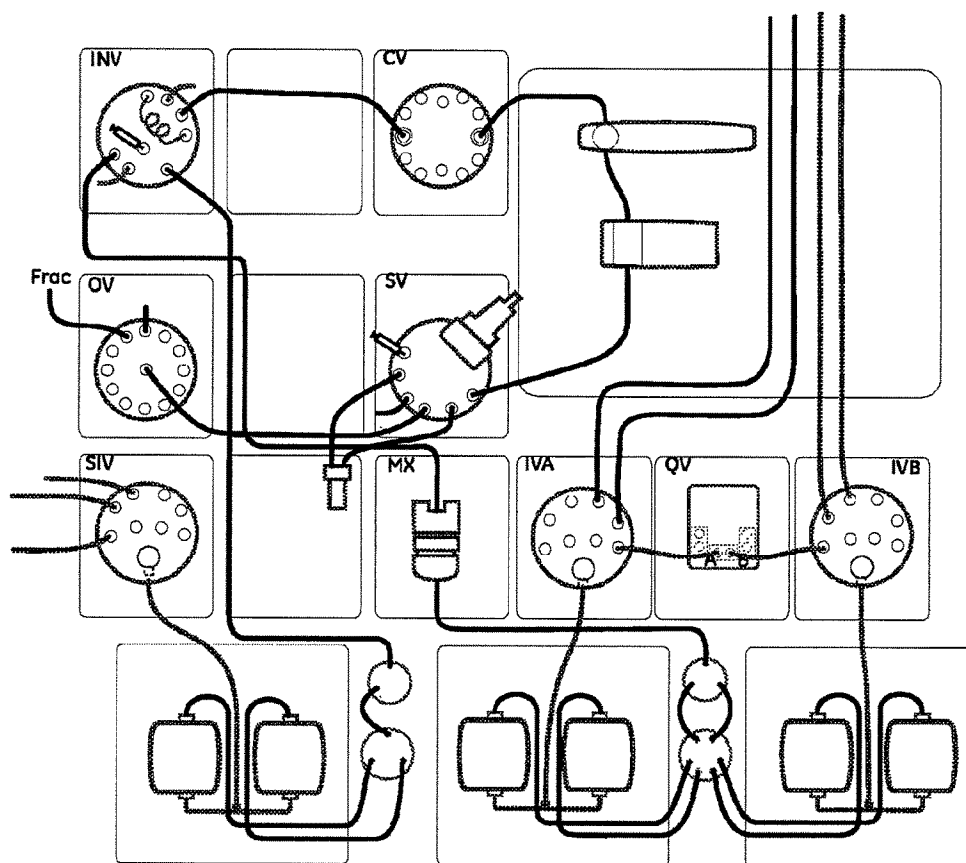


Fig. 10



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## AUTOMATED FLUID HANDLING SYSTEM

**Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.**

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a filing under 35 U.S.C. §371 and claims priority to international patent application number PCT/SE2010/050624 filed Jun. 4, 2010, published on Dec. 16, 2010 as WO 2010/144037, which claims priority to application number 0950431-7 filed in Sweden on Jun. 9, 2009.

## BACKGROUND OF THE INVENTION

The present invention relates to the art of fluid handling system systems, and in particular to an automated fluid handling system that is highly flexible and configurable. The fluid handling system may e.g. be a liquid chromatography system, a filtration system, a chemical synthesis system or the like.

There is a large range of fluid handling systems e.g. in laboratories. Such systems comprise a number of fluid handling units, e.g. one or more pumps, valves, mixers, sensor units etc of different types. Said fluid handling units are interconnected by fluid conduits in the form of, rigid or flexible tubes or the like. Even though some systems may be designed for a specific type of application with a specific flow path, there often exists a need for flexibility and ability to alter or optimize the fluid flow path of the system. Moreover, upgrading is often restricted to specific kits provided by the manufacturer, and upgrade kits often is supplied as external add-on equipment to be arranged besides the original system, thus enlarging the foot print of the system and that need to be connected to the system both fluidically and electrically (i.e. to a system control bus or the like). Moreover, replacement of defect fluid handling units is a time consuming and delicate task.

One type of liquid handling system is liquid chromatography systems which is a standard method in laboratories, and there are a broad range of liquid chromatography systems available on the market. Common to most of the present systems is the lack of flexibility in adapting the instrument to a variety of different applications.

## SUMMARY OF THE INVENTION

The object of the invention is to provide a new fluid handling system, which system overcomes one or more drawbacks of the prior art. This is achieved by the fluid handling system as defined in the independent claims.

One advantage with such a fluid handling systems is that the system may easily be upgraded without need for add-on equipment, and that the flow path may be easily optimized for new experimental setups.

Embodiments of the invention are defined in the dependent claims.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows one embodiment of a fluid handling system in the form of a liquid chromatography system, according to the present invention.

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FIG. 2 is a schematic illustration of a housing with a liquid handling panel of the fluid handling system of FIG. 1.

FIG. 3 is a schematic illustration of the housing with the liquid handling panel of FIG. 2 with the modular components of the fluid handling system removed.

FIGS. 4a to 4d are schematic illustrations of examples of component modules of the fluid handling system removed.

FIGS. 5a and 5b show a schematic embodiment of an automated fluid handling system.

FIG. 6 is a schematic illustration of an embodiment of a housing with a modular liquid handling panel with the modular components of the fluid handling system removed.

FIGS. 7a and 7b are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with the modular components of the fluid handling system removed.

FIG. 8 is a schematic illustration of an embodiment of the system architecture of one embodiment of a fluid handling system according to the present invention.

FIG. 9 is a schematic illustration of an embodiment of a master control unit of one embodiment of a fluid handling system according to the present invention.

FIG. 10 is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel for the liquid chromatography system of FIG. 1.

## DETAILED DESCRIPTION OF THE INVENTION

According to one embodiment, there is provided an automated fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components with an external fluidics section and an internal non fluidics section, and wherein the housing comprises a liquid handling panel with two or more of component positions for receiving said interchangeable modular components such that the external fluidics section is separated from the non fluidics section by the liquid handling panel.

According to another embodiment, there is provided a fluid handling system in the form of a liquid chromatography system comprising a housing, two or more high pressure pumps, at least one sensor unit and a plurality of fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components and the housing comprises a liquid handling panel with a plurality of component positions for receiving said modular components.

FIG. 1 shows one embodiment of an automated fluid handling system modular in the form of a liquid chromatography system, with a plurality of interchangeable modular components arranged in a liquid handling panel wherein the reference numbers denotes:

1. Injection valve
2. Column valve with integrated pressure sensors
3. Conductivity monitor
4. UV monitor
5. Quaternary valve
6. Inlet valve B with integrated air sensor
7. System pump
8. Pressure monitor, system pump
9. Inlet valve A with integrated air sensor
10. System pump
11. Pressure monitor, sample pump
12. Sample pump
13. Rinsing system

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- 14. Mixer with online filter
- 15. Sample inlet valve with integrated air sensor
- 16. Flow restrictor
- 17. pH valve
- 18. Outlet valve

The disclosed embodiment is supplied with three high precision pumps 7, 10, 12. There are two System pumps 7, 10, System pump A 10 and System pump B 7, and one Sample pump 12. The System pumps 7, 10 may be used individually, or in combination to generate isocratic or gradient elution in purification methods. The Sample pump 12 is dedicated for direct loading of sample onto a column, or for filling of sample loops.

#### Function of the Pumps:

Each pump module consists of two pump heads (not shown). The individual heads are identical but actuated in opposite phase to each other by individual stepper motors, controlled by a microprocessor. The two pistons and pump heads work alternately to give a continuous, low pulsation, liquid delivery. The flow rate of the two System pumps may be varied between about 0.001 ml/min and 25.000 ml/min and the maximum operating pressure is about 20 MPa. The flow rate of the Sample pump may e.g. be varied between 0.01 and 25 ml/min and according to one embodiment the maximum operating pressure is 10 MPa.

According to one embodiment, the plurality of fluid control valves of at least two different configurations are valves of rotary type. Such a motorized rotary valve may consist of a Valve head with a number of defined bores with channels to the inlet and outlet ports of the valve. The Rotary disc, mounted on the motor, has a number of defined channels. The pattern of channels of the Rotary disc together with the pattern and location of the ports of the Valve head, define the flow path and function of each type of valve. When the Rotary disc turns, the flow path in the valve changes.

One embodiment of fluid control valves are Inlet valves A and B (9, 6 respectively) that are used to select which buffers or samples to use in a run, and Sample inlet valve 15 that is located before Sample pump 12. Inlet valve A 9 is located before System pump A 10, inlet valve B 6 is located before System pump B 10, and Sample inlet valve 15 is located before Sample pump 12. Inlet valve A and Inlet valve B are connected to another embodiment of a fluid control valve in the form of a Quaternary valve 5. The Quaternary valve is used for automatic buffer preparation, and for formation of quaternary gradients. The number of inlets can be increased by installing component modules with extra inlet valves. Inlet valve A and Inlet valve B enable automatic changing between different buffers and wash solutions, and can be used to generate gradients by mixing buffer A and buffer B. The air sensors integrated in Inlet valve A and Inlet valve B can be used to prevent introduction of air into the pumps and columns.

The Quaternary valve is used for automatic mixing of four different solutions. The Quaternary valve opens one inlet port at a time, and the different solutions are mixed in a Mixer 14 to form the desired buffer. The opening time in the switching valve is controlled by the system. The volume for each inlet port opening increases stepwise when the flow increases. To obtain a homogeneous buffer composition, one has to make sure to use a mixer chamber volume suitable for the flow rate of the method.

The Quaternary valve can be used to create a gradient using four different solutions simultaneously in any combination. The percentage of each solution is controlled by instructions in the method. It is possible to form gradients

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that changes the percentage of two, three or four solutions linearly over time. This is useful when advanced methods are developed.

The Sample inlet valve 15 enables automatic loading of different samples when using the Sample pump 12 to inject sample directly onto the column or to fill a sample loop. The Sample inlet valve has an inlet dedicated for buffer. This Buffer inlet is used in methods to fill the Sample pump with solution before sample is introduced. The Buffer inlet is also used to wash the Sample pump with buffer between runs. The air sensor integrated in the Sample inlet valve is e.g. used when sample is applied from a vessel onto a column by selecting Inject all sample using air sensor in the Sample application phase of a method. This function uses the Buffer inlet is used to finalize sample injection and to remove air from the Sample pump.

Still another embodiment of fluid control valve may be an Injection valve 1, which is used to direct sample onto the column. The valve enables usage of a number of different sample application techniques. A sample loop can be connected to the Injection valve and filled either automatically using the Sample pump or manually using a syringe. The sample can also be injected directly onto the column using the Sample pump.

Still another embodiment of fluid control valve may be a Column valve 2 that is used for connection of columns to the system, and to direct the flow onto the column. Up to five columns can be connected to the disclosed embodiment of said valve simultaneously. The valve also has a built-in bypass capillary that enables bypassing of connected columns.

The number of column positions can be increased by installing an extra Column valve. Both top and bottom of each column shall be connected to the Column valve. The top of the column shall be connected to one of the A ports (e.g., 1A), and the bottom of the column shall be connected to the corresponding B port (e.g., 1B). The flow direction can be set either from the top of the column to the bottom of the column, Down flow, or from the bottom of the column to the top of the column, Up flow. In the default flow path of the Column valve the columns are bypassed. Pressure monitors that measures the actual pressure over the column are integrated into the inlet and outlet ports of the Column valve.

Still another embodiment of fluid control valve may be a pH valve 17 that has an integrated flow cell where a pH electrode can be installed. This enables in-line monitoring of pH during the run. A flow restrictor is connected to the pH valve and can be included in the flow path to generate a backpressure high enough to prevent formation of air bubbles in the UV flow cell. The pH valve is used to direct the flow to the pH electrode and to the flow restrictor, or to bypass one or both.

Still another embodiment of fluid control valve may be an Outlet valve 18 that is used to direct the flow to a Fraction collector (not shown), to any of e.g. 10 outlet ports, or to waste. The number of outlets can be increased by installing an extra Outlet valve.

A Mixer 14 may e.g. be located after System pump A and System pump B and before the Injection valve. The purpose of the Mixer is to make sure that the buffers from the System pumps are mixed to give a homogenous buffer composition. The Mixer has a built-in filter that prevents impurities from entering the flow path.

To fulfil a desired purpose, with the disclosed liquid chromatography system it is possible to adapt and extend the flow path in a simple and a flexible way. Up to three extra

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fluid control valves or the like can be installed using the free valve positions. Dummy modules are installed in these positions at delivery. To obtain an optional flow path, it is also possible to move the standard fluid control valves to other positions. There are also two types of extra air sensors available which can be installed before Sample inlet valve or after Injection valve.

In the configuration disclosed in FIG. 1, 7 inlets are available for each inlet valve. To increase the number of inlets, an extra inlet valve can be installed which increases the number of inlets to 14 for one of the valves. This optional configuration can be convenient for example when a larger number of samples will be used. There is also a general type of inlet valve, Valve X, which can be used to increase the number of inlets to for example the Quaternary valve.

In the configuration disclosed in FIG. 1 with one column valve, 5 column positions are available. To increase the number of column positions to 10, an additional column valve can be installed in the instrument. An application can be to evaluate a number of different columns in method optimization.

In the configuration disclosed in FIG. 1 with one outlet valve, 10 outlet positions are available. To increase the number of outlets, one or two extra outlet valves can be connected, adding up to a total of 21 or 32 outlet positions. This optional configuration is convenient when collecting a number of large fractions outside the fraction collector.

Optional modules are easy to install in the disclosed modular liquid chromatography system. The dummy module is removed with a hexagon wrench and a bus cable is disconnected. The bus cable is connected to the optional fluid control valve or the like which is assembled in the instrument. The module is then added to the System properties in the control software. The available optional modules may e.g. be pre-configured to give the desired function. However, the function of a valve may e.g. be changed by changing the Node ID.

FIG. 2 is a schematic illustration of a housing 20 with a liquid handling panel 22 of the fluid handling system in the form of a modular liquid chromatography system 100 of FIG. 1. In FIG. 2 some components have been removed for clarity reasons. In the disclosed configuration, as disclosed in detail above, the modular liquid chromatography system 100 comprises a plurality of fluid control valves in the form of: Injection valve 1, Column valve 2, Quaternary valve 5, Inlet valve B 6, Inlet valve A 9, Sample inlet valve 15, pH valve 17, and Outlet valve 18. The chromatography system 100 further comprises UV monitor 4, System pump B 7, System pump A 10, Sample pump 12, Mixer 14, and three Dummy modules 24. According to one embodiment, all liquid handling components and sensors arranged at the liquid handling panel 22 are designed to be readily interchangeable. The interchangeability provides improved service and upgrade possibilities and also a possibility to customize the positions of the respective liquid handling components, such as the fluid control valves, e.g. in order to optimize the fluid path for a specific experimental setup. As is illustrated in FIG. 2, there are three large component positions e.g. for pump modules, one UV-sensor position and 9 standard component positions, e.g. for fluid control valves or the like. The component positions are given a standardized size and shape to provide simple interchangeability. According to one embodiment, each modular component is retained in a mating component position by a single screw, and it is connected to the master control unit by a single bus cable providing both communication and system power to each component. FIG. 3 is a schematic

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illustration of the housing with the liquid handling panel of FIG. 2 with the modular components of the liquid chromatography system removed.

FIGS. 4a to 4d are schematic illustrations of examples of fluid handling units in the form of modular component of the fluid handling system removed. FIG. 4a shows a standard interchangeable modular component 26, e.g. a fluid control valve or the like. The standard component module 26 comprises a panel member 28, an external fluidics section 30 and an internal non-fluidics section 32. According to one embodiment, the panel member 28 essentially separates the fluidics in the external fluidics section 30 from electronics and control means in the internal non-fluidics section 32.

FIG. 4b shows a Dummy module 24, which is intended to be placed in non used standard component positions. In the disclosed embodiment, the Dummy modules are provided with mounting grooves for attachment of accessories to the system. In the disclosed embodiment the dummy module is shown as a panel member 28 without any internal section. FIGS. 4c and 4d shows a pump module and an UV-module, respectively, each having an external fluidics section 30 and an internal non-fluidics section 32.

As is disclosed in FIGS. 4a to 4d, the interchangeable modular components 26 comprises a panel member arranged to separate the fluidics section from the non fluidics section and for attachment to a component position in the liquid handling panel. Said panel attachment member may be arranged so that all fluid connections of said modular component are arranged on a wet side of the panel attachment member separating them from electrical components that are arranged on a dry side thereof, hence providing a high degree of liquid resistance at the external part of the fluid handling panel, and so that the liquid resistance requirements for the internal sections may be somewhat lightened. According to one embodiment, the interchangeable modular components are sealed against the liquid handling panel by a sealing member. According to another embodiment, not shown, the modular component does not comprise any panel member, but there is provided a suitable sealing arrangement between the component position openings of the liquid handling panel and the external surface of the interchangeable modular components 26. In the disclosed embodiments, the component position openings of the liquid handling panel and the interchangeable modular components 26 are shown to have an essentially rectangular cross sectional shape, but other shapes may be equally applicable.

According to one embodiment, there is provided a general fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components as is schematically disclosed in FIG. 5a. As discussed above such a system may be configured for essentially any type of automated liquid handling operations provided that suitable fluid handling units are provided as interchangeable modular components for the system. According to one embodiment there is provided an automated fluid handling system comprising at least one fluid pump, at least one sensor unit and two or more fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components.

The liquid handling panel 22 of the fluid handling system may e.g. be designed in any suitable manner to allow the modular components to be arranged in an efficient manner.

FIGS. 5a and 5b shows a schematic embodiment of an automated fluid handling system wherein the housing 20 comprises an internal climate panel 29 arranged at a distance

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behind the liquid handling panel 22 defining an air inlet compartment 35 and air outlet compartment 37 in the housing 20, the climate panel 29 being provided with complementary component positions 39 for receiving the internal non fluidics section 32 of the interchangeable modular components 26, and wherein the non-fluidics section 32 of at least one interchangeable modular component is provided with one or more air inlet openings 31 located in the air inlet compartment 35 and one or more air outlet openings 33 located in the air outlet compartment 37 when the interchangeable modular component arranged in position in the component position. FIG. 5b shows the fluid handling system of FIG. 5a in a schematic cross sectional view. As is indicated by inlet vent 41 and outlet vent 43, air for cooling interchangeable modular components 26 provided with air inlet and outlet openings 31, 33 is preferably arranged to enter the air inlet compartment 35 at a distance from the outlet vent 43 in order to avoid recirculation of air. The air circulation in the system may be achieved by a system cooling unit (not shown) providing a flow of air from the air inlet compartment 35 to the air outlet compartment 37, through the at least one interchangeable modular component 26. Alternatively, the at least one interchangeable modular component 26 is provided with a local cooling unit (not shown) providing a flow of air from the air inlet compartment 35 to the air outlet compartment 37. As is indicated, the complementary component positions 39 are arranged to provide a relatively air flow tight fit with respect to the internal non fluidics section 32 of the interchangeable modular components 26, and according to one embodiment, this may be achieved by a sealing arrangement. In FIG. 5b, there is shown a sealing member 45 for sealing the interchangeable modular components 26 with respect to the liquid handling panel 22, as discussed above. Other sealing member arrangements may be envisaged by a person skilled in the art. According to one embodiment, fluids are strictly restricted to the fluidics section 30 of the interchangeable modular component 26, but in alternative embodiments, only fluid connections are restricted to the fluidics section 30 allowing fluid to "cross" the fluid handling panel inside the non-fluidics section 30 of the interchangeable modular component 26.

In FIG. 5b there is further shown a master control unit 40 and buss connectors 42 for connecting the interchangeable modular components 26 to the master control unit 40. According to one embodiment, the component positions including the buss connectors 42 and the interchangeable modular components 26 are of plug and play configuration with respect to each other.

FIG. 6 is a schematic illustration of an embodiment of a housing 20 with a modular liquid handling panel 22 with the modular components of the liquid chromatography system removed. In the disclosed embodiment, also the layout of the liquid handling panel 22 is configurable by means of two interchangeable panel sections 34 which may be selected in accordance with the desired layout of the system. In FIG. 6 two different layouts of the interchangeable panel sections are disclosed, but the layout may include any suitable configuration.

FIGS. 7a and 7b are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with the modular components of the liquid chromatography system removed. In the disclosed embodiment, the modular housing is comprised of a main housing 36 that comprises the master control unit including power supply and climate control for the whole housing, two expansion housing modules 38 and a side member 40. This approach provides very

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flexible expansion possibilities for the chromatography system, while preserving the benefits of a single master control unit including power supply and climate control.

FIG. 8 is a schematic illustration of an embodiment of the system architecture of one embodiment of a modular liquid chromatography system according to the present invention. As mentioned above, the chromatography system may comprise a master control unit 40 arranged to communicate with all modular components e.g. 1-26, over a system bus 42 such as a CAN-bus or the like. In one embodiment, each modular component is provided with a dedicated CPU unit allowing the component to independently perform operations in response to instructions over the BUS 42. In order to minimize the number of connectors to be attached to each modular component, the bus 42 further comprises power feed for the modular components. The Bus 42 may be connected to any suitable number of modular components arranged in the housing 20, but also to one or more modular components 44 outside of the housing 20 or the like. As is mentioned briefly above, the master control unit may further be arranged to control the climate in the housing. In addition to the disclosed modular components, other components of the chromatography system, e.g. a fraction collector or the like, may be arranged in the housing and the controlled climate therein.

According to one embodiment, different component modules are automatically identified by the master control unit, whereby they may be moved essentially freely between different positions. Moreover, the master control unit may be arranged to provide said information to Chromatography control software whereby experimental setup and planning may be performed. In one embodiment, the control system may be arranged to provide an optimized layout of the component modules with respect to the present layout of the liquid handling panel and available component modules for a specific experimental setup.

According to one embodiment, the interchangeable panel sections 34 of FIG. [5] 6 and the expansion housing modules 38 of FIGS. [6a] 7a and [6b] 7b may be provided with means for automatic detection of the same to allow automatic configuration of the system by the master control unit 40. In one embodiment, each interchangeable panel section 34 and expansion housing module 38 comprises a hub (not shown) for connection to the system bus 42 in order to expand the system bus 42 network to the number of component modules in each interchangeable panel section 34 or expansion housing module 38.

FIG. 9 is a schematic illustration of an embodiment of a master control unit of one embodiment of a modular liquid chromatography system according to the present invention. The master control unit 40 comprises a system controller 46 for communicating with internal and external components and control computers (not shown) etc. According to one embodiment, the system controller comprises a suitable CPU 48, a bus controller 52, an external communications controller 50, such as a LAN unit, and a storage device 54. The bus controller 52 is providing communication with the component modules. The master control unit may further comprise a Power supply 56 and a climate controller 58 arranged to keep the internal climate in the housing 20 at a predetermined level as discussed above.

FIG. 10 is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel. Taking into account the complexity of the disclosed interconnection arrangement, the benefit of optimizing the fluid paths in alternative configurations of the system becomes evident.



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The task of optimizing the fluid paths may e.g. be performed to reduce the total length/volume of the fluid paths/tubing arranged to interconnect the different component modules in the system. Alternatively the optimization may be performed to minimize the length/volume of one or more specific fluid paths, such as the sample output path from the column to the fraction collector, in order to minimize dispersion of the fractionized sample.

The invention being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the following claims.

What is claimed is:

[1. Automated fluid handling system comprising a housing and two or more interchangeable fluid handling units the housing comprising a liquid handling panel including two or more component positions for receiving said interchangeable units, wherein said units are arranged as interchangeable modular components, and include:

a fluidics section;

a non fluidics section comprising electronics or electrical components or control means; and

a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel,

and wherein the two or more component positions of the liquid handling panel are arranged for attachment of the panel members such that said respective fluidics sections are external to the housing and said respective non fluidics sections are internal to the housing.]

[2. The fluid handling system of claim 1, wherein the interchangeable modular components are sealed against the liquid handling panel by a sealing member.]

[3. The fluid handling system of claim 1, comprising a master control unit wherein the interchangeable modular components are connected to the master control unit by a system bus providing electrical communication to each interchangeable modular component.]

[4. The fluid handling system of claim 1, wherein all interchangeable modular components are of same size.]

[5. The fluid handling system of claim 1, wherein the interchangeable modular components are of two or more sizes.]

[6. The fluid handling system of claim 1, comprising at least one fluid pump, at least one sensor unit and two or more fluid control valves of at least two different configurations, wherein at least the fluid control valves comprise said interchangeable modular components.]

[7. The fluid handling system of claim 3, wherein the master control unit comprises a system climate controller for controlling the climate in the housing and the interchangeable modular components.]

[8. The fluid handling system of claim 1, wherein the housing comprises an internal climate panel arranged spaced from the liquid handling panel within the housing, said internal climate panel defining on one side an air inlet compartment and defining on an opposing side an air outlet compartment in the housing, the climate panel being provided with complementary component positions for receiving the internal non fluidics section of the interchangeable modular components, and wherein the non-fluidics section of at least one interchangeable modular component is provided with one or more air inlet openings located in the air inlet compartment and one or more air outlet openings

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located in the air outlet compartment when the interchangeable modular component is arranged in position in the component position.]

[9. The fluid handling system of claim 8, further comprising a system cooling unit providing a flow of air from the air inlet compartment to the air outlet compartment, through said at least one interchangeable modular component.]

[10. The fluid handling system of claim 8, wherein said at least one interchangeable modular component is provided with a local cooling unit providing a flow of air from the air inlet compartment to the air outlet compartment.]

[11. The fluid handling system of claim 1, wherein the system is a liquid chromatography system arranged to provide a controlled fluid flow through a chromatography column.]

[12. The fluid handling system of claim 1, wherein the system is a liquid filtration system.]

[13. The fluid handling system of claim 1, wherein the system is a chemical synthesis system.]

[14. The fluid handling system according to claim 1 wherein the system further comprises at least one expansion housing module for accommodating additional interchangeable modular components.]

[15. The fluid handling system according to claim 14, further including means for automatic detection of said module to allow automatic configuration of the system by a master control unit.]

16. A liquid chromatography system arranged to provide a controlled fluid flow through a chromatography column, the system comprising a housing and two or more interchangeable fluid handling units, the housing comprising a liquid handling panel including two or more component positions for receiving said interchangeable units, wherein said units are arranged as interchangeable modular components, and include:

a fluidics section;

a non fluidics section in turn comprising electronics or electrical components or control means; and

a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel,

and wherein the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing.

17. The liquid chromatography system according to claim 16, wherein the interchangeable modular components include at least [one] two of: an injection valve; a column valve with integrated pressure sensors; a conductivity monitor; a UV monitor; a quaternary valve; an inlet valve with integrated air sensor; a system pump; a pump pressure monitor; [an inlet valve with integrated air sensor]; a rising valve; a mixer; a filter; a sample inlet valve; a flow restrictor; a pH valve; an outlet valve; [and] or a dummy component.

18. The liquid chromatography system according to claim 17, wherein said modular components are interconnected fluidically on the external side of the panel.

19. The liquid chromatography system of claim 16, wherein the interchangeable modular components are sealed against the liquid handling panel by a sealing member.

20. The liquid chromatography system of claim 16, comprising a master control unit wherein the interchangeable modular components are connected to the master control unit by a system bus providing electrical communication to each interchangeable modular component, and wherein

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each of the interchangeable modular components includes a dedicated CPU unit allowing each of the interchangeable modular components to independently perform operations in response to instructions over the bus.

21. The liquid chromatography system of claim 16, wherein all interchangeable modular components are of same size.

22. The liquid chromatography system of claim 16, wherein the interchangeable modular components are of two or more sizes.

23. The liquid chromatography system of claim 16, comprising at least one fluid pump, at least one sensor unit and two or more fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components.

24. The liquid chromatography system of claim 20, comprising at least one fluid pump, at least one sensor unit and two or more fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components.

25. The liquid chromatography system of claim 16 wherein the system further comprises at least one expansion housing module for accommodating additional interchangeable modular components at the liquid handling panel.

26. The liquid chromatography system of claim 16, wherein the housing includes at least four component positions.

27. The liquid chromatography system of claim 26, wherein the at least four component positions are arranged in a two dimensional array.

28. The liquid chromatography system of claim 16, comprising  
two double piston pumps,  
one injection valve for injecting sample onto a column  
connecting to the flow path of the liquid chromatography system,  
a UV monitor, and  
a mixer.

29. The liquid chromatography system of claim 28, wherein the pump, valve, monitor, and mixer are interchangeable modular components.

30. The liquid chromatography system of claim 28, wherein the system further includes  
a pH-valve with an integrated flow cell for in-line monitoring of pH levels, and  
a quaternary valve for automatic buffer preparation and formation of quaternary gradients.

31. The liquid chromatography system of claim 25, wherein the expansion housing module is attached to the housing and comprises two or more component positions adapted to receive additional interchangeable modular components at the liquid handling panel.

32. The liquid chromatography system of claim 31, wherein the component positions of the expansion housing module are arranged to receive interchangeable modules of the same size.

33. The liquid chromatography system of claim 31, wherein the component positions of the expansion housing module are arranged to receive interchangeable modules of two or more sizes.

34. The liquid chromatography system of claim 31, wherein the component positions of the expansion housing module comprise at least four component positions.

35. The liquid chromatography system of claim 16, wherein the fluidics section comprises one or more fluid connectors for connecting the interchangeable fluid handling unit to a fluid flow path of the liquid chromatography system,

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and the non fluidics section comprises an enclosure housing the with one or more air inlet openings.

36. The liquid chromatography system of claim 20, wherein the internal fluidics section comprises a bus connector for directly connecting the interchangeable modular component with the system bus, and each component position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus.

37. The liquid chromatography system of claim 16, wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two are interchangeable modular components.

38. A liquid chromatography system arranged to provide a controlled fluid flow through a chromatography column, the system comprising a housing, a master control unit connected to a system bus, two double piston pumps, and two or more interchangeable fluid handling units, the housing comprising a liquid handling panel including two or more component positions for receiving said interchangeable units, wherein said units are arranged as interchangeable modular components, and include:

a fluidics section;  
a non fluidics section in turn comprising electronics or electrical components or control means, and including a bus connector for directly connecting the interchangeable modular component with the system bus; and  
a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the interchangeable modular component to a component position of the liquid handling panel,

wherein the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing, wherein each component position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus,

wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus, wherein the master control unit is arranged to automatically identify interchangeable modular components, wherein the system includes at least a valve and a mixer as interchangeable modular components, wherein the system is capable of performing automated liquid chromatography.

39. The liquid chromatography system according to claim 38, wherein said interchangeable modular components are interconnected fluidically on the external side of the panel.

40. The liquid chromatography system of claim 38, wherein the interchangeable modular components are sealed against the liquid handling panel by a sealing member.

41. The liquid chromatography system of claim 38, wherein the housing includes at least four component positions arranged in a two dimensional array.

42. The liquid chromatography system of claim 38, wherein the system further comprises at least one expansion housing module for accommodating additional interchangeable modular components at the liquid handling panel.

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43. The liquid chromatography system of claim 38, wherein said housing is further adapted to include at least one sensor unit and at least two fluid control valves of different configurations, of which at least the sensor unit, and the fluid control valves are interchangeable modular 5 components.

44. The liquid chromatography system of claim 38, wherein the fluidics section comprises one or more fluid connectors for connecting the interchangeable fluid handling unit to a fluid flow path of the liquid chromatography 10 system, and the non fluidics section comprises an enclosure housing the with one or more air inlet openings.

\* \* \* \* \*

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# **EXHIBIT 37**



IN THE UNITED STATES DISTRICT COURT  
IN AND FOR THE DISTRICT OF DELAWARE

- - -

GE HEALTHCARE BIO-SCIENCES : CIVIL ACTION  
AB, GE HEALTHCARE :  
BIO-SCIENCES CORPORATION, :  
and GENERAL ELECTRIC :  
COMPANY, :  
Plaintiffs, :  
vs. :  
BIO-RAD LABORATORIES, INC., :  
Defendant. : NO. 18-1899-CFC

- - -

Wilmington, Delaware  
Thursday, May 14, 2020  
10:30 o'clock, a.m.  
\*\*\*Telephone conference

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

- - -

APPEARANCES:

SHAW KELLER LLP  
BY: JOHN W. SHAW, ESQ.

-and-

Valerie J. Gunning  
Official Court Reporter

1 APPEARANCES (Continued) :

2  
3 ARNOLD & PORTER KAYE SCHOLER LLP  
4 BY: JENNIFER SKLENAR, ESQ.  
(Washington, D.C.)

5 -and-

6  
7 ARNOLD & PORTER KAYE SCHOLER LLP  
8 BY: JEFFREY A. MILLER, ESQ.  
(Palo Alto, California)

9 Counsel for Plaintiffs

10  
11 POTTER, ANDERSON & CORROON LLP  
12 BY: ALAN R. SILVERSTEIN, ESQ. and.  
DAVID E. MOORE, ESQ.

13 -and-

14  
15 QUINN EMANUEL URQUHART & SULLIVAN, LLP  
16 BY: DAVID BILSKER, ESQ. and  
17 FELIPE CORREDOR, ESQ.  
(San Francisco, California)

18 Counsel for Defendant

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20  
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1 P R O C E E D I N G S

2  
3 (The telephone conference commenced at  
4 10:30 a.m.)

5  
6 THE COURT: All right. Good morning, counsel.  
7 Can we have a roll call from the plaintiffs,  
8 please?

9 MR. SHAW: Good morning, Your Honor. It's this  
10 is John Shaw from Shaw Keller for plaintiffs.

11 Joining me from Arnold & Porter are Jennifer  
12 Sklenar and Jeffrey Miller.

13 MS. SKLENAR: Good morning.

14 THE COURT: Good morning. All right. And the  
15 defense?

16 MR. SILVERSTEIN: Good morning, Your Honor.  
17 Alan Silverstein from Potter Anderson for defendant.

18 With me on the line is my colleague, David  
19 Moore, and David Bilsker and Felipe Corredor from Quinn  
20 Emanuel. Also on the line is John Katzenham, in-house  
21 counsel for Bio-Rad.

22 THE COURT: All right. Thanks very much.

23 Okay. Do you want to start? We'll begin with  
24 the interchangeability modularity terms, and I do want to  
25 try to be brief. I've read carefully the briefing, so let's

1 start with the plaintiffs, please.

2 MS. SKLENAR: Good morning, Your Honor. This is  
3 Jennifer Sklenar. If I can just start.

4 We have agreed with the other side to do the  
5 groupings if we look at the joint brief, terms 8 through C  
6 first, and then D, and then as a second grouping, and then  
7 as the third, E through G, and then the fourth, H and I.  
8 But, of course, we're happy to take it in whatever grouping  
9 your Honor would prefer.

10 THE COURT: Right. So let's start with the  
11 interchangeability. I think that corresponds with what you  
12 just said anyway.

13 MS. SKLENAR: Yes. We will do that. So I will  
14 turn it over to Mr. Miller, who is going to address the  
15 first and fourth grouping.

16 MR. MILLER: Excuse me. Good morning, Your  
17 Honor. This is Jeffrey Miller from Arnold & Porter, and I'm  
18 going to start by referring to our slide deck, which  
19 Mr. Shaw e-mailed to your chambers yesterday, and I'm going  
20 to start on slide 6, which just refers to the proposed  
21 constructions from each side and then we can move on to a  
22 basic concept of the law here, which is that this term is  
23 something that has never been used before in this field, and  
24 that opens up all of the intrinsic record to be used when  
25 trying to construe this term. So that means that the

1 prosecution history, the specification, the claim language,  
2 it's all used, and importantly, you don't have to show any  
3 kind of disclaimer to use those items the from the intrinsic  
4 record, and sometimes you'll seen this referred to in the  
5 case law as a coined term and we have some case law laid out  
6 for you in slide 7 on that.

7 And there's no evidence in the record that this  
8 term interchangeable modular component or the other similar  
9 terms are anything other than a coined term. Bio-Rad hasn't  
10 proposed any, or hasn't shown any evidence that this term  
11 was used before GE, which is now actually called Cytiva,  
12 used it or anyone else did.

13 So I want to turn your attention to slide 10,  
14 which shows a figure from the five patents that are in this  
15 case and I think sort of lay the groundwork for what this  
16 invention is about and helps understand this term.

17 So just real briefly. GE started developing  
18 this system in 2003. It's listed on the liquid  
19 chromatography products, and it recognized early on that a  
20 big problem was that these systems were extremely difficult  
21 to modify once they were out in the field. They would  
22 generally require a serviceperson to come in and install new  
23 components, which could take as much as a day or two, and so  
24 if you wanted to change the functionality of your system or  
25 run different experiments, it was very cumbersome to try to

1 change what was going on, change the structure of the  
2 system, and so that's when they developed this  
3 interchangeability concept.

4 And you can see in slide 10 one of the  
5 embodiments they had come up with, and you can see the  
6 various positions in the front panel there and there are  
7 callout numbers with reference numerals there and you can  
8 see those little rectangles. Each of those is an  
9 individualized changeable fluid, interchangeable modular  
10 component.

11 And the way in practice this would work is that  
12 the customer, not a serviceperson from the company, would  
13 come out, would put the various components where they wanted  
14 to put them in order to make the experiment run as smoothly  
15 as possible. And it's not shown in the figure of the  
16 patent, but the way you would finalize the experiment would  
17 be to run tubing between the various components.

18 So you see that there are across the first row  
19 at the top, there are four interchangeable modular  
20 components, and if you wanted to run fluid from, for  
21 example, the upper left-hand corner to the interchangeable  
22 component marked as two and then on to number four, you  
23 would run tubing, and the user could put that tubing into  
24 little receptacles that are on those components and they  
25 could run the tubing.

1           So this was a lot easier than having to open up  
2           a cabinet or a housing and move things around and so it  
3           makes it much easier. Sometimes we refer to these things as  
4           being plug and play, sort of like your old PC cards. You  
5           could put things in one slot or the next one you could  
6           move some component, move them into a different  
7           slot.

8           So let's move on to slide 11, because this also  
9           highlights what we're talking about here. So on slide 11,  
10          we've modified Figure 2 of the patent just to remove the  
11          reference numerals and you can see across the top there's an  
12          interchangeable modular component referred to as an inlet  
13          valve and then right below that there's an outlet involve.  
14          Right below that there's a sample inlet valve, and to the  
15          right of the sample inlet valve, there's a mixer, et cetera,  
16          et cetera. There's all kinds different components with  
17          different functionality involved in this particular  
18          embodiment.

19          And on the right-hand side we've excerpted a  
20          portion of Figure 8 from the '589 patent and you can see  
21          that there's all different types of components. And in the  
22          real world what happens is that if you're a customer, say  
23          you're a pharmaceutical company and you want to work through  
24          a protein purification run, you only need to buy the  
25          interchangeable modular components that you think you're

1 going to need, but if later on you find out that you needed  
2 an additional mixer or a cautionary valve or whatnot, you  
3 could buy more of them and then you could rearrange them in  
4 the system as you saw fit. You wouldn't have to have Cytiva  
5 or GE come to your facility to do that for you. You could  
6 do it yourself.

7 Let's move on to slide 12, and this text from  
8 the specification highlights what this is all about. So you  
9 can see it says, the present invention relates to the art of  
10 fluid handling systems, and in particular to an automated  
11 fluid handling system that is highly flexible and  
12 configurable.

13 So this highlights an aspect of our construction  
14 that we feel is important, which is that the interchangeable  
15 modular components have to have the ability to have  
16 different functionality to be placed at various locations.

17 THE COURT: Okay. So let me interrupt. So I'm  
18 looking at this excerpt. Where is the must? Where is the  
19 language in the written description that says there's a  
20 requirement that there has to be a different functionality  
21 as opposed to that it would allow for different  
22 functionality?

23 MR. MILLER: Well, the point is, is that you  
24 don't have -- so let's say this is being used in a  
25 production facility. You probably never would change the



1 position of the various components. The point of the  
2 construction is that in order to meet the limitation of the  
3 claim, you have to have that ability. So I don't know that  
4 the word must appears anywhere in the patent, but certainly  
5 it's a requirement of the system, of the module that you  
6 have that ability.

7 THE COURT: Okay.

8 MR. MILLER: Okay. And that's when the  
9 specification here talks about something be highly flexible  
10 and configurable, that's what it means.

11 We can go on to slide 13. I think you're going  
12 to be hearing Bio-Rad talk about this portion as well.  
13 They focus on the first portion of the sentence, which  
14 says that the interchangeability provides improved service  
15 and upgrade possibilities, so if the module breaks, you  
16 could put just another one in with the same functionality,  
17 but they don't address the portion that follows, which says,  
18 and also a possibility to customize positions of the  
19 respective liquid handling components, such as the valves  
20 and whatnot, in order to --

21 THE COURT: Let me just go back, though. Look,  
22 if it doesn't have must, you're saying it just has to allow  
23 for it. So then why do we have to interpret the way you do?  
24 Why don't we just leave it the way Bio-Rad wanted?

25 MR. MILLER: Because I think what Bio-Rad would

1 say, in other words, under Bio-Rad's construction, they  
2 would not be -- it's not even -- excuse me. Under Bio-Rad's  
3 construction, it doesn't have to have that ability. In  
4 other words, Bio-Rad's construction would cover the  
5 situation where --

6 THE COURT: No, they can't. Under Bio-Rad's  
7 construction, it could have that ability, it could be for a  
8 different functionality, but it doesn't have to be.

9 MR. MILLER: It doesn't have to be, that's what  
10 they say, but it doesn't even have to have the ability to.  
11 That's the point, which is that in order for the word  
12 interchangeably to have any meaning at all, you have to be  
13 able to interchange them into various different places. In  
14 other words, the claim does not say changeable. It says,  
15 interchangeable, interchangeably, so you need to be able to  
16 move them from one position to another and the specification  
17 stresses that.

18 THE COURT: Right. But you admit, right,  
19 Bio-Rad's construction would allow for the other component  
20 to have a different functionality. Right?

21 MR. MILLER: It doesn't exclude that  
22 possibility.

23 THE COURT: Right. So therefore, because you  
24 just said it doesn't have to have must, it just has to allow  
25 for it. Well, then, their construction allows for it. It

1 allows for a different functionality.

2 MR. MILLER: Well, that's like saying I  
3 have a claim that requires the element A. If I also have  
4 the element B, it's not excluded, but that doesn't mean  
5 that the claim requires it.

6 In the specification, the prosecution history  
7 over and over again stressed the importance of being able to  
8 change the position of the modules, which means that they  
9 would have to be able to have different functionality.

10 THE COURT: I don't get it. Go ahead.

11 MR. MILLER: Okay. Well, if you look at -- I'm  
12 going to move on now to Figure 14, and I think this might  
13 help Your Honor.

14 So, I'm sorry, slide 14. So in slide 14, we've  
15 got Figure 10 from the patent and the specification which  
16 repeatedly talks about being able to optimize fluid flow  
17 path.

18 Bio-Rad, if you look at slide 15, this is an  
19 excerpt from their brief, they talk about being able to  
20 move, just shorten up the tubing, and that would optimize  
21 fluid flow path, and that's not what the patent is talking  
22 about. The patent is making it clear that the way you  
23 optimize fluid flow path is being able to move these into  
24 the various different positions.

25 So I would like to move on to our slide 19, and

1 I think this also helps, would help Your Honor with this  
2 concept of interchangeability.

3 So slide 19 refers to a portion of the  
4 specification, and in the yellow here we've highlighted a  
5 portion that Bio-Rad relies on, and they rely pretty  
6 heavily on this. But you need to take the entire portion  
7 of this piece of the specification in context, which is  
8 that if you look at the green part, so the green part says  
9 that taking into account the complexity of the disclosed  
10 interconnection arrangement, the benefit of optimizing  
11 fluid paths in alternative configurations becomes evident.  
12 And, again, this demonstrates that the specification is  
13 teaching you that you need to be able to move these  
14 positions, these interchangeable modular components into  
15 different positions.

16 All right. So I would like to move on to --

17 THE COURT: But their construction doesn't  
18 preclude that.

19 MR. MILLER: Well, it doesn't preclude it, but  
20 it doesn't require it, and it's clear from the specification  
21 this is an important function of the invention.

22 THE COURT: Well, of course. I don't think  
23 there's any doubt it's an important function, but what  
24 about, look at column 1 of the patent, and it talked about  
25 replacing defective fluid handling units. Right? It's

1 replacing. It says that the invention is designed to  
2 overcome that. So that's an important part of the  
3 invention, too. Right?

4 MR. MILLER: All that would mean is that we can  
5 modify our construction to being able to say that it  
6 requires that you replace them and interchange them. That  
7 doesn't mean you don't read the important, read one  
8 important aspect in and another out.

9 THE COURT: No, but theirs reads both in whereas  
10 yours doesn't.

11 MR. MILLER: Yes, but their construction is  
12 broader than what the specification requires. In other  
13 words --

14 THE COURT: But yours precludes it. You're  
15 precluding embodiments where there's just a replacement.

16 MR. MILLER: No, we're not. You could take  
17 their argument and flip it on its head.

18 If the argument is that ours exclusively calls  
19 out changing -- change of functionality, it doesn't say you  
20 can't replace. It's just not making it required. Again,  
21 that argument would say that you just take, you construe the  
22 claim to require both replaceability and interchangeability.  
23 We frankly would be fine with that, but that's just adding  
24 words into the claim -- into the construction.

25 Okay. Let me move on to the prosecution history

1 because I think this further demonstrates what's going on  
2 here.

3 If you go to -- we have an excerpt here in slide  
4 22. And remember, this is a coined term. You don't need to  
5 have a full-blown disavowal. So we have a coined term here,  
6 and here's a portion of the prosecution history where the  
7 inventors were distinguishing their invention from the  
8 Mourtada prior art reference, which you are going to hear  
9 about a fair amount today.

10 So it says in Mourtada, and Mourtada is actually  
11 an exhibit, I believe it's Exhibit G. Mourtada had these  
12 giant cassettes where it had valves and sensors and whatnot  
13 kind of all part of the same cassette, and the Examiner took  
14 the position that that was an interchangeable modular  
15 component because you could just pull it out and put another  
16 one in.

17 And --

18 THE COURT: You know, you just said that. I  
19 thought you said this is a coined term of art.

20 MR. MILLER: Well, they were not called  
21 interchangeable modular components.

22 THE COURT: I thought the Examiner called it  
23 that.

24 MR. MILLER: The Examiner, as is pretty common  
25 during prosecution, the Examiner said that this piece of

1 prior art -- I'm reading. This structure that's in  
2 Mourtada, and I'm saying that it's an interchangeable  
3 modular component, didn't use that -- the reference itself  
4 didn't use the term interchangeable modular component.

5 So anyway -- I'm sorry. Mourtada is Exhibit I.

6 In Mourtada, you had these very large cassettes,  
7 and you could, if something broke or whatnot, you could pull  
8 it out and put another one in, or these were complicated  
9 things. It was some kind of a radio isotope system, and you  
10 could pull it out and rearrange some of the cloning and  
11 whatnot and insert them again.

12 So what the patent attorney did here when  
13 distinguishing Mourtada, he specifically said, and we have  
14 this quote on slide 22 and it's Exhibit G of the patent --  
15 of our materials here. It says, while the cassettes, and he  
16 is referring to Mourtada, are replaceable or exchangeable  
17 with a differently configured cassette, in other words, you  
18 could rearrange the tubing or whatnot, they are not  
19 interchangeable with other components in the apparatus, and  
20 this was confirmed in the drawings.

21 And so, for example, if you go to Figure 10 --  
22 excuse me. Figure 9 is a good example of this. So in  
23 Figure 9, there's this giant cassette 105, which takes up  
24 almost the entire panel there. You could pull that whole  
25 thing out and you could either replace it with one that's

1 not broken anymore or you could rearrange, you know, pull it  
2 out, rearrange all the tubing and put it back in again. But  
3 the point was, is that it had the same functionality, the  
4 underlying cassette.

5 And so even during prosecution, the patent  
6 attorney was arguing that there's a difference here between  
7 interchangeability and replaceability, and  
8 interchangeability was an important aspect with the  
9 invention, which is, as we discussed, stressed throughout  
10 the specification.

11 So I think if you go to slide 23, I think this  
12 addresses the question you had for me earlier. So in our  
13 construction, we require that there be interchangeability.  
14 So, in other words, you have to be able to, for example,  
15 replace the inlet valve B, which is shown on the left-hand  
16 side, with the outlet valve.

17 Our construction doesn't exclude the possibility  
18 of doing replacements, so if you want to just replace one  
19 outlet valve for another outlet valve, which is see on the  
20 right-hand side, that is -- that's not excluded from our  
21 construction.

22 Now, I want to address another point in their  
23 brief.

24 THE COURT: Just so I'm clear, their  
25 construction doesn't preclude the interchangeability of



1 components with different functionality.

2 MR. MILLER: Yes, it does not preclude that.

3 That's true.

4 THE COURT: Right.

5 MR. MILLER: And in the specification, you know,  
6 under that view, we should just frankly not construe it at  
7 all because it doesn't mean anything. In other words, the  
8 specification says, hey, look, I have this thing here which  
9 you've never heard of before called an interchangeable  
10 modular component and these are the important features. One  
11 is that you should be able to replace them, and another,  
12 which is the one we're focusing on, you need to be able to  
13 put it in different positions so you can optimize fluid flow  
14 and that means there's going to be different functionality.  
15 That's an important thing to understand when instructing the  
16 jury. Otherwise, they're going to be left that, you know,  
17 that feature is going to be sort of left that the -- no one  
18 is going to be -- it's not going to be focused on and it is  
19 an important aspect of the invention, and it opens up  
20 potential prior art and what not, which frankly in this  
21 situation it wouldn't be fair because we distinguished the  
22 prior art by making this exact argument.

23 THE COURT: Well, actually, this has nothing to  
24 do with the jury. Right? You're taking the position  
25 because this is all about invalidity, isn't it?

1 MR. MILLER: Well, certainly, I think that  
2 Bio-Rad is going to take the position that this  
3 interchangeable modular component could be any blob that  
4 they say it is. Like I said, if they want to construe -- if  
5 Your Honor wants to construe the term to require both of  
6 these important features, that would be fine with us. We  
7 are focusing on the one that really was not in the prior  
8 art, which is the interchangeability of different functions,  
9 components.

10 THE COURT: But my point is that, that has  
11 nothing to do with infringement. When you say this is a  
12 jury question, you point out how it's important to make it  
13 clear to the jury. I mean, correct me if I'm wrong, this  
14 has got nothing to do with the jury. This is all about  
15 invalidity, or nothing about infringement, I should say.  
16 It's all about invalidity.

17 In fairness, I think I just confused things  
18 because the jury would be deciding invalidity. But this is  
19 not an infringement issue is what I'm getting at. Right? I  
20 mean, this is all about invalidity.

21 MR. MILLER: That's probably correct, Your  
22 Honor. I mean, I think that they want to have an  
23 extraordinarily broad understanding of what one of these  
24 components could be to try to bring in more prior art.

25 THE COURT: Right. And normally, that's the

1 plaintiff, but we've got the opposite situation here. We  
2 have a plaintiff trying to argue for a narrow interpretation  
3 of these claims.

4 MR. MILLER: I mean, I don't really know that  
5 we're trying to narrow. We're just trying to read it in  
6 view of what the specification and the prosecution history  
7 say, which is that they need to have different functions,  
8 because in order to move them around, they need different  
9 functions.

10 So, in other words, this is not a term that  
11 whoever is making the decision is going to say, yes, I  
12 know what that is and I'm going to know what it means.  
13 Right? In other words, so, you know, the experts who  
14 have never heard of this term before we started using  
15 these patents because it was never used before. So what  
16 does it mean?

17 So it's clear from the specification that both  
18 of these functions were important. The ability to take out  
19 a broken one and replace it with a new one was not  
20 unimportant. You pointed to those portions of the  
21 specification out as well, but it was also important that  
22 they be able to move them around. In other words, so if  
23 you -- you know, if you draw -- if you take an element and  
24 you say, well, I'm sorry. My analogy escapes me at the  
25 moment. But if you just say that, you know, a personalized

1 motor vehicle is a nice broad term, right, that might ignore  
2 the fact that the patent is saying that it has to be a  
3 two-wheeled, you know, change ribbon, you know, apparatus.  
4 Right?

5 So if you construed the -- if you just say it's  
6 whatever this thing is, you know, this very broad concept  
7 and you construe it that way but it's clear that the  
8 specification and the prosecution said it was something  
9 narrower, the claim should be construed to refer to what's  
10 actually described in the patent, especially here, when we  
11 don't have a term that has any common understanding. It was  
12 never used before. This is an important part of the  
13 invention.

14 So I just wanted to raise a couple more points  
15 unless you have any other questions.

16 So if you go to slide 25 and 26, all the claims  
17 require that there be at least two, at least three or at  
18 least four of these interchangeable modular components,  
19 and Bio-Rad made an argument that that means that however  
20 many there are, they all have to be interchangeable. In  
21 other words, a good way of thinking about this is if you  
22 had a system that has eight positions in it with eight  
23 different -- had the ability to receive eight different  
24 interchangeable modular components, even though the claim  
25 says that there only has to be at least two of them,

1 Bio-Rad's position is that all eight of them in the system  
2 would have to be interchangeable with each other. And  
3 that's -- frankly, we think that's not a good argument,  
4 because basically what they are saying is that if you had a  
5 system with eight and seven of them could be interchanged  
6 with various, into various different positions, they could  
7 design around their system by just making one of them fixed  
8 in position, and that's plainly -- that would lead to a  
9 bizarre result.

10 And then --

11 THE COURT: Wait. Sorry. Say that again. You  
12 are saying if they could design around -- I'm just trying to  
13 figure out how it relates to all -- tell me that again.

14 MR. MILLER: Okay. So let me start again.

15 So the interchangeable modular components need  
16 to be -- you have to be able to put them into various  
17 different locations inside the, you know, in the housing.  
18 So if you look at, for example, Figure 1 or Figure 2. Why  
19 don't we look at Figure 2. It's probably easier.

20 So in Figure 2, in the upper left-hand corner,  
21 you have this inlet valve, and then two spots away from  
22 that, you have a -- you have, excuse me. You have the  
23 control valve, number two. I'm sorry. So let's say -- so  
24 let's focus on the claims. It requires at least two of  
25 these.

1           So here, there would be at least two  
2   interchangeable modular components, but as you see, there's  
3   a number of different other locations inside this chassis,  
4   and so under our construction, at least two means that if  
5   you sell a system that has two interchangeable modular  
6   components, even if there are all of these other  
7   positions -- you know, let's assume for argument's sake  
8   that number 6 on the far right-hand side, the inlet valve  
9   B --

10           THE COURT: Yes.

11           MR. MILLER: -- let's say that for whatever  
12   reason, that position was fixed and you could not put a  
13   different type of component in it. Under Bio-Rad's argument  
14   that all of them have to be interchangeable modular  
15   components, they would have a noninfringement argument  
16   because they would be saying it's like, yeah, I know the  
17   claim says that it only requires at least two, but their  
18   view is that at least two means the system has to have two,  
19   but all of the components within the system have to have the  
20   same ability, and that would be, frankly, I think a silly  
21   result.

22           Does that make sense?

23           THE COURT: Show me where in the claim are they  
24   pointing to, that that all must exist?

25           MR. MILLER: Well, that's a good point, but if

1     you look at the brief on page 33, we have this reprinted on  
2     slide 25.

3                 THE COURT:   Okay.   Hold up.   Page 33 of the  
4     brief?

5                 MR. MILLER:   Reprinted on slide 25.

6                 THE COURT:   I mean, I'm just kind of confused.  
7     They are going to say, I think, that the premise of your  
8     hypothetical is wrong, that the IVB, if it's stationary,  
9     it's not one of these interchangeable components.   So why is  
10    there a design-around?

11                MR. MILLER:   Well, their view, if you look at  
12    their brief, they say a system -- it only has to have -- you  
13    can sell a system with two.   It would fall within the scope  
14    of the claim.   That's what they would say.   But if you sold  
15    the system with four, even though the claim says at least  
16    two, the claim requires that all four be interchangeable,  
17    and that defies the claim language.

18                The claim language says that the system only has  
19    to have at least two that qualify as these interchangeable  
20    modular components.   So what they are doing is trying to  
21    rewrite the claim.

22                So let me -- so, you know, if you take -- you  
23    know, let's just focus in on, if you look at claim 16 of the  
24    reissued patent, it says that there's a liquid  
25    chromatography system arranged to provide a control fluid

1 flowthrough --

2 THE COURT: Wait, wait. I'm on the '589. What  
3 patent are you on now?

4 MR. MILLER: I can go to the '589, too. It  
5 doesn't matter.

6 THE COURT: All right.

7 MR. MILLER: They're all --

8 THE COURT: So you probably want to look at  
9 claim 1 of the '589, maybe?

10 MR. MILLER: Sure. So it says that -- it says  
11 an automated liquid chromatography system comprising a  
12 housing unit and at least four modular fluid handling units.

13 THE COURT: Okay.

14 MR. MILLER: In the preamble.

15 THE COURT: Now, under your hypo, IVB is not a  
16 modular fluid handling unit. Right?

17 MR. MILLER: Under our hypo --

18 THE COURT: You said it's stationary or can't  
19 move. It's stuck in there.

20 MR. MILLER: Yes. I mean, this is what Bio-Rad  
21 would say, is that as long as -- if the system has four,  
22 that's fine. Right? But if there are five, all five have  
23 to meet requirements of what is stated here as at least four  
24 modular components.

25 So, in other words, we say that the claim



1 requires that they all be able to be interchangeable.  
2 Right? Their position is that, well, if I add a fifth one  
3 and my system doesn't have -- has one that can't be moved,  
4 then there's no infringement, because even though it says at  
5 least four, if I add a fifth, that one wouldn't meet the  
6 limitations of the claim, and that's crazy.

7 I mean, it says that the claim uses the word  
8 comprising in the transition, and so that's well understood  
9 to mean that, you know, all the claim requires is what's  
10 specifically stated, and if you add additional items, that  
11 doesn't get you around infringement.

12 So, in other words, if there are four that meet  
13 the definition of an interchangeable modular component, the  
14 fact that there's a fifth position in the system that has a  
15 component of some kind that does not meet the definition of  
16 an interchangeable modular component, that doesn't mean that  
17 you all of a sudden don't infringe.

18 THE COURT: All right.

19 MR. MILLER: Okay. So I just want to address  
20 one more item, which is the IPR.

21 THE COURT: I'm not going to -- I mean, you  
22 don't want me to consider the IPR. Right?

23 MR. MILLER: Something that's applicable here,  
24 it's a different standard.

25 THE COURT: I agree. You know what? I mean, I

1 don't think I need to consider the IPR to make my decision,  
2 so let's just skip over the IPR.

3 MR. MILLER: Okay. Well, unless you have any  
4 other questions from me, I think that's all I need to say  
5 about this particular term.

6 THE COURT: All right. Let's hear from the  
7 other side.

8 MR. CORREDOR: Good morning, Your Honor. Felipe  
9 Corredor on behalf of Bio-Rad.

10 I think that Your Honor hit, really hit the nail  
11 on the head. When we were looking at the spec, the  
12 specification during plaintiffs' presentation, which is, if  
13 we start on our slides at slide 6, I think there's a key  
14 passage that plaintiffs were discussing earlier.

15 The language that the specification uses is all  
16 about possibility. There's no mandatory requirement or need  
17 to be able to do any of these things. It's just these are  
18 things that are possible thanks to the interchangeability,  
19 and it includes --

20 THE COURT: Well, let me ask you this. Let me  
21 just interrupt for a second. So a couple things.

22 So, one, are you arguing plain and ordinary  
23 meaning?

24 MR. CORREDOR: Yes. We think that is, our  
25 proposed construction is the plain and ordinary meaning of

1 interchangeably modular component, yes.

2 THE COURT: Where do you say that in your brief?

3 MR. CORREDOR: I'm not sure we say it  
4 explicitly.

5 THE COURT: So why didn't you? I mean, that's  
6 usually the starting point when somebody argues plain and  
7 ordinary meaning, which is the starting point in  
8 construction. Right? They say it explicitly. Why didn't  
9 you say it here?

10 MR. CORREDOR: Well, I think the plain and  
11 ordinary meaning of the term is always in light of the  
12 specification. Right? So I think the starting point  
13 according to Phillips is in order to determine what the  
14 plain and ordinary meaning is is the specification and the  
15 claims, and I think that's where we started in the brief,  
16 was a discussion of the term in the context of the  
17 specification and the claims.

18 THE COURT: But also on other terms, parties,  
19 GE, for instance, page 68 of the brief, the wherein the  
20 system is capable of performing automated liquid  
21 chromatography says it's the plain and ordinary meaning.  
22 That seems normal. Why didn't you do that here?

23 MR. CORREDOR: Well, why didn't we propose a  
24 construction? I see your question.

25 So I think --

1 THE COURT: No. I mean, I thought you were  
2 going to tell me you're going to admit it's not the plain  
3 and ordinary meaning and you are not arguing for it because  
4 it's not in your brief, but now you're telling me you really  
5 are? You are asserting this is the plain and ordinary  
6 meaning of the term?

7 So do you agree? I mean, can you show me  
8 anywhere where the term interchangeable, where you can --  
9 excuse me, where you can show me that interchangeable  
10 modular component exists in the prior art before these  
11 patents?

12 MR. CORREDOR: The specific phrase  
13 interchangeable modular component, no, but the component,  
14 words that make up that phrase, are known and used in the  
15 art, and, in fact, GE itself pointed to a dictionary  
16 definition before the PTAB about what interchangeable meant  
17 and they include things that hit on that. But I mean at  
18 that time, I think there was a plain and ordinary meaning to  
19 the words that make up this phrase.

20 THE COURT: Okay. So let's just close the loop  
21 here. You are now arguing plain and ordinary meaning. Is  
22 that what you are saying?

23 MR. CORREDOR: Yes, but we think the proposal we  
24 provide clarifies for the jury what it means, because a lay  
25 jury will not necessarily understand the phrase

1 interchangeable modular component alone.

2 THE COURT: Okay. What does modular mean?

3 MR. CORREDOR: So I think modular in our  
4 construction, if we put up slide 3 of our deck, we have the  
5 both sides' discussion.

6 So I think some of the terms use only modular in  
7 some of the claims, so at the bottom. So I think that's  
8 what we would say modular means. Modular means something  
9 that has a standardized size and shape that allows it to be  
10 exchanged with another unit.

11 THE COURT: All right. So then interchangeable  
12 must mean something different than modular. Right?

13 MR. CORREDOR: Yes.

14 THE COURT: So what does interchangeable mean  
15 that is different than module, modular?

16 MR. CORREDOR: I think modular is about the  
17 standardized size and shape. When we look at the top where  
18 it's construing interchangeable, that it can be inserted and  
19 removed from positions in the housing. So modular is the  
20 standardized size and shape, but it can also be inserted and  
21 removed from positions in the housing.

22 THE COURT: You say in your definition on slide  
23 3, you say under modular, it has a standardized size and  
24 shape that allows it to be exchanged with another. How is  
25 that different than it can be inserted into and removed from

1 positions in the housing unit?

2 MR. CORREDOR: Well, I think it would help to  
3 look at the figures to understand the difference between  
4 the two. So Figure 2, for example, on slide 8 of our deck.

5 THE COURT: Okay.

6 MR. CORREDOR: The difference is that a modular  
7 unit is something that can be removed and replaced with  
8 something else.

9 THE COURT: All right.

10 MR. CORREDOR: Whereas, because of its  
11 standardized size and shape. For example, I could remove  
12 the outlet corner number 1, the INV valve. I could remove  
13 it and put another INV valve in and that's a modular unit.

14 The interchangeability means that now we have to  
15 actually be able to -- the INV valve, I no longer want at  
16 the top left corner. I'm going to take it out and move it  
17 to the second position, to the right of where it currently  
18 is, and I think that is the interchangeability portion that  
19 we're talking about.

20 THE COURT: I'm having a hard time understanding  
21 the difference between that and modular. Why isn't that  
22 just modular?

23 MR. CORREDOR: I think that's -- that's correct  
24 for unit 4, because 4 I think would be modular. I think the  
25 difference between the two is a very slight difference and

1 I'm not sure there's a dispute between the parties as to  
2 that.

3 THE COURT: Well --

4 MR. CORREDOR: I think --

5 THE COURT: I think the point would be if -- I  
6 mean, I think what the plaintiffs want to argue, I didn't  
7 hear them argue it. I mean, interchangeable goes to  
8 functionality maybe. Modular goes to the standardized size  
9 and shape.

10 MR. CORREDOR: They have not proposed that, so  
11 that's not in their language. Right? So I don't think that  
12 is a dispute between the parties. And the parties actually  
13 in their brief, in the plaintiffs' brief, they said, I  
14 mean, you can just construe modular for the handling unit  
15 the same way as you do the other two terms that have  
16 interchangeable in them. There's no difference, and the  
17 patent nowhere according to the plaintiffs themselves in  
18 their briefs, and I don't have the pin cites, the term means  
19 the same thing.

20 THE COURT: Right.

21 MR. CORREDOR: And I think we would agree with  
22 that. If Your Honor is inclined to construe them the same  
23 way --

24 THE COURT: Well, they didn't make the argument,  
25 so let's go ahead. All right.

1 MR. CORREDOR: All right. So I think I was  
2 discussing the specification. So, yes.

3 THE COURT: All right.

4 MR. CORREDOR: I was reiterating the point I  
5 made earlier, which is on slide 6. The fact that the  
6 specification only uses permissive possibility language and  
7 not mandatory requirements or anything like that anywhere in  
8 the specification.

9 THE COURT: And you don't dispute that given  
10 what you just said, that the other unit could have a  
11 different functionality. Your point is just it doesn't have  
12 to?

13 MR. CORREDOR: Exactly, yes. So our point is it  
14 can have different functionality. It can have the same  
15 functionality. Either one is fine. Either one meets our  
16 proposed construction. However, plaintiffs' proposed  
17 construction is only met by one of those two, and both of  
18 them, both of those possibilities serve as an upgrade,  
19 were designed, and according to the specification in column  
20 1, to solve problems in the prior art. So both are  
21 important to the invention.

22 THE COURT: Okay. So here's how I'm going to  
23 rule. I'm going to rule in your favor. And the question  
24 here is does the intrinsic evidence provide objective  
25 boundaries to the scope of the disputed terms, and here the



1 intrinsic evidence shows that the patentee did not limit the  
2 scope of the term such that the other component had to have  
3 different functionality. The claims themselves don't  
4 require different functionality.

5 If you look at the written description, which is  
6 shared by all of the patents, so I will refer to the '589  
7 patent. And if you look particularly to column 1, lines 39  
8 to 42 and lines 50 to 52, the invention was designed to  
9 overcome problems in the prior art, and one of those  
10 problems was the replacement of defect -- that's a typo, I  
11 guess, defective handling units, which the written  
12 description described as time-consuming and delicate, a  
13 delicate task.

14 And then if you look at column 5, lines 53 to  
15 54 of the patent, there it references the  
16 interchangeability, that interchangeability provides  
17 improved service as well as upgrade possibilities. That's  
18 clearly not limiting. That could be contemplating clearly  
19 the same part being, a part rather being exchanged that  
20 shared the functionalities, had the same functionality.

21 I think then there's also a problem with the  
22 plaintiffs' position in that its proffered construction  
23 would exclude two embodiments. And then if you look here  
24 where the patent discussed, summarizes Figure 2, and it  
25 says, according to -- and this is quoting from column 5, all

1 liquid handling components and sensors arranged at the  
2 liquid handling panel are designed to be readily  
3 interchangeable.

4 And further, "The interchangeability provides  
5 the improved service and upgrade possibilities and also a  
6 possibility to customize the positions of the respective  
7 liquid handling components such as the fluid control valve.  
8 For example, in order to optimize the fluid path for  
9 specific experimental setup."

10 Then if you look to the interchangeable modular  
11 components, they include the UV monitor 4, whose  
12 standardized sizes and shapes differs from all the other  
13 disclosed interchangeable modular components.

14 So clearly, it was contemplating then the  
15 substitution or the exchange of only, or the substitution or  
16 exchange of a component that had the exact same  
17 functionality. A UV monitor 4 would only be interchangeable  
18 with another UV monitor component, so that would be in order  
19 to replace a defective UV monitor. And you have the same  
20 situation with regard to the pump system. And so the  
21 plaintiffs' position essentially would read out these  
22 embodiments.

23 The plaintiff relies heavily on iridescent  
24 networks and insists that we have a coined term here, but we  
25 don't have a coined term of degree, which is what iridescent

1 networks is addressing. And also the bottom line is, as the  
2 Court said in Iridescent Networks is, I am required to  
3 consider whether the intrinsic evidence provides objective  
4 boundaries, and here, as I've explained, it doesn't provide  
5 objective boundaries that would lead to the conclusion that  
6 you must have different functionality.

7 And I just don't find that the distinguishing of  
8 Mourtada during the prosecution history constitutes anything  
9 clear or unequivocal, and at most it's an ambiguous  
10 discussion and it would not, in my view, trump the more  
11 powerful intrinsic evidence, which is set forth in the  
12 written description that I've already discussed.

13 Okay. Let's move to the preambles that are  
14 limiting, which I think is the second category. Here, let  
15 me hear briefly from the defense.

16 MR. CORREDOR: Yes, Your Honor. It's Felipe  
17 Corredor again.

18 Okay. I'm not following my notes.

19 Your Honor, I guess the key dispute here between  
20 the parties regarding the liquid chromatography term has to  
21 do with whether the preambles are limiting, and if I may  
22 turn your attention to slide 21 of our, of the deck Bio-Rad  
23 submitted.

24 Here, they are trying to deviate from the  
25 general rule that the preambles are not limiting. Now, they

1 have a set of different reasons for it, and let me go  
2 through one by one why none of their reasons support making  
3 the preambles limiting.

4 Turning next to slide 22, the first basis they  
5 say is an antecedent basis. Now, in their argument, I think  
6 it's important to note that the antecedent basis they point  
7 to is only in a few scattered dependent claims and not in  
8 the independent claims, which really are the core of the  
9 invention.

10 And moreover, as the Federal Circuit has stated  
11 in cases such as Summit 6, which is cited in our brief and  
12 shown here on slide 22, that the antecedent basis is not  
13 enough.

14 And so the claim at issue in Summit 6 had a  
15 preamble that decided a computer implemented method for --

16 THE COURT: Let me just interrupt. Let me just  
17 interrupt because we want to be mindful of the time here. I  
18 mean, Summit, there was no antecedent basis. Is that  
19 correct?

20 MR. CORREDOR: There is an antecedent basis for  
21 the client device. Right. So that client device throughout  
22 the body of the claims are referring back to a client device  
23 in the preamble.

24 THE COURT: So you're saying there was an  
25 antecedent basis in Summit?

1 MR. CORREDOR: Yes, and the Federal Circuit  
2 still found the preamble not to be limiting.

3 THE COURT: Okay.

4 MR. CORREDOR: All right. So that's the main  
5 point for Summit 6.

6 THE COURT: Can you show me where -- I just want  
7 to make clear so I can find it. Where in Summit 6 does it  
8 talk about there being an antecedent basis?

9 MR. CORREDOR: Yes. Let me pull that case up.

10 I think the claim at issue is on slide 22.  
11 Right? It's claim 38. And, yes. The issue the Federal  
12 Circuit was deciding on page 22 of Summit 6 has to do with  
13 claim 38, which is the one that was depicted in slide 22,  
14 and it had an antecedent base for a client device in the  
15 preamble.

16 THE COURT: I'm sorry. I'm reading it. It  
17 says, does not contend that the preamble to claim 30 is  
18 necessary for providing an antecedent basis.

19 MR. CORREDOR: Yes. The parties may not have  
20 contended that, but I mean the use of said was throughout  
21 the claim, which is also recited in pages 1287 to 88 of the  
22 case. It's pretty clear that the client device found an  
23 antecedent basis in the preamble.

24 THE COURT: Okay.

25 MR. CORREDOR: And I think more importantly,

1 this is -- all the cases that have been cited by the  
2 parties, and especially by plaintiff, have to do with  
3 antecedent basis in the independent claims, and here there  
4 are no independent claims that rely on the preamble for  
5 antecedent basis. It's only in a few scattered, I think a  
6 scattered dependent claim among the, I think they've  
7 asserted 120 to 130 claims in this case.

8 THE COURT: Okay.

9 MR. CORREDOR: So if you have no other questions  
10 on antecedent basis, I will move on to the next reason that  
11 we provided for making the preamble limiting.

12 THE COURT: Okay.

13 MR. CORREDOR: It is the -- on slide 25, if you  
14 will turn your attention to slide 25.

15 Now, this is a case that I think is important.  
16 This underlies the point. I just wanted to read a passage  
17 from it, which is at pages 1372 through 73 of Proveris,  
18 which makes clear that the only reference in any independent  
19 claim of the inventive concept of capturing of images was in  
20 the preamble. So the important aspect, the inventive aspect  
21 in Proveris was claimed only in the preamble and that is why  
22 it had to be limiting.

23 Here, by contrast, if we switch to the next  
24 slide, slide 26, the specification, the language that  
25 appears in the preamble is liquid chromatography. Right?

1 And the specification tells us that actually liquid  
2 chromatography is not something that they have invented.

3 If you look at column 1 starting at line 41, it  
4 says, one type of liquid handling system, the liquid  
5 chromatography system, which is a standard method in  
6 laboratories, and there are a broad range of liquid  
7 chromatography systems available on the market. And when  
8 you go down a little bit more, line 48 under the summary of  
9 the invention, I think it tells us that the provide a new  
10 fluid handling system overcoming the drawbacks we discussed  
11 in the context of the previous term, which have to do with  
12 the modularity and interchangeability.

13 So I think the focus of the invention here is on  
14 modularity and interchangeability, not on liquid  
15 chromatography, and that is why I think the specification  
16 for why liquid chromatography in the claims would not  
17 breathe life or meaning into the claims, so that is not also  
18 a satisfactory reason for making the preamble limiting.

19 Next I think is the structure point, and I think  
20 there's a lot of -- I mean, the plaintiffs keep saying --

21 THE COURT: I am having a hard time. I look at  
22 your slide 28. I mean, it opens up and it says, what's  
23 claimed is an automated liquid chromatography system  
24 comprising.

25 This is a matter of common sense. How is it not

1 that everything else that follows is part of a claimed  
2 automated liquid chromatography system? How does that not  
3 give life, meaning, vitality to the claim?

4 MR. CORREDOR: I think the way you've phrased  
5 the question, I think the body of the claims are what is  
6 giving life, meaning to the preamble. So if you really --  
7 reading the preamble alone, an automated liquid  
8 chromatography system, we have no idea what that is. There  
9 is no structure associated with it. The only structure is  
10 the one defined within the body of the claim, comprising the  
11 housing unit, and for modular handling unit with each of  
12 those components having several additional features recited  
13 throughout the body of the claim.

14 So it really -- I don't think anything in the  
15 preamble breathes life or meaning into the body of the  
16 claims, and if it did, I mean, a lot of system claims  
17 started with a system. For example, Arctic Cat started just  
18 like that. A personal recreational vehicle comprising, and  
19 there was a bunch of special limitations in the claim.

20 So the invention both in Arctic Cat and in this  
21 case are especially defined as especially complete  
22 inventions in the body of the claims without any reference  
23 for reliance upon the preamble language. I think that's the  
24 key portion, the key part of why --

25 THE COURT: You broke up. You broke off



1 completely. You said without any reference and then you  
2 broke off.

3 MR. CORREDOR: Well, without any reference or  
4 reliance on the preamble language, and Arctic Cat  
5 recreational vehicle here liquid chromatography system. I  
6 think that is the key point, that all the structural  
7 features are in the body of the claim. And I don't think  
8 I've seen anything from plaintiffs about what additional  
9 structure the preamble provides that is not already recited  
10 in the body of the claims, and I think that's an important  
11 reason why it cannot be limiting.

12 So I think Arctic Cat, just a note on Arctic Cat  
13 on slide 29. I think slide 29, that claim in Arctic Cat was  
14 the one that is more closely analogous, especially in light  
15 of Your Honor's question. It really is, you know, extremely  
16 analogous to this case, and plaintiffs certainly focus on  
17 other claims in Arctic Cat, which makes the use and not  
18 structural language clearer. For example, on slide 30,  
19 where it's clear that the personal recreational vehicle is a  
20 mere use. But all the claims in Arctic Cat were found to  
21 have a preamble that was not limiting.

22 I think just to go over a few of the other cases  
23 that plaintiffs have cited, if I can direct your attention  
24 to slide 34. They relied on Pacing Technology, and here  
25 there's again a clear antecedent basis, the user, the user,

1 and so that is a distinguishing feature.

2 And then in Electro Scientific Industries on  
3 slide 35, I think here we see what a structural component  
4 that appears in the preamble would be, and here, the  
5 preamble says, in a tool positioning system that is  
6 implemented as part of a working processing system in which  
7 the work pieces are electronic circuit boards, the tool  
8 positioning system, et cetera, comprising.

9 So the circuit boards are a structural  
10 component. They really are something that has -- that adds  
11 to what is recited in the body of the claim.

12 And seeing In re Fought on slide 36, which is  
13 recited, a travel trailer having, indicating the body of the  
14 claim, and the travel trailer there was found on page 1177,  
15 I believe, to a structure, meaning it had to be portable and  
16 it had to have living quarters and portability and living  
17 quarters are not found anywhere in the body of the claim  
18 depicted here. So I think that distinguishes, you know,  
19 plaintiffs' prior cases.

20 So there is no antecedent basis -- there is --  
21 the invention is defined as a structurally complete  
22 invention in the body of the claims, of the independent  
23 claims, and not without reliance on the preamble. I think  
24 the combination of these and what has been found to be  
25 limiting in prior cases and what has not really indicates

1 that the liquid chromatography language in this claim, the  
2 claim at issue here or the claims at issue here, do not  
3 breathe life, meaning, life or meaning to the claim, and I  
4 think that is why we submit the claim, the preamble should  
5 not be limiting.

6 THE COURT: Okay. Thank you.

7 MR. CORREDOR: Thank you, Your Honor.

8 THE COURT: I will hear from the plaintiff.

9 MS. SKLENAR: Yes. Thank you, Your Honor. This  
10 is Jennifer Sklenar.

11 This is an important issue. All of the claims  
12 that are recited have liquid chromatography systems somehow  
13 in the preamble, but there are systems for that, or their  
14 methods for performing or building those type of systems.

15 And if we go to our slide, slide 35 --

16 THE COURT: How about when he says there's no  
17 structure except in the dependent claims?

18 MS. SKLENAR: Well, I think that they have not  
19 cited a case that supports that. Right? When we get to  
20 dependent claims, we do have many claims. In fact, one  
21 claim that every patent recites liquid chromatography system  
22 in the body of the claim. As a matter of patent law, that  
23 means you have to read that as referring back to whatever  
24 it's referencing back, which here is the preamble of the  
25 independent claim.

1           So when you read those dependent claims, you  
2           have to read it with the independent claim. That means the  
3           preamble of the independent claim must be a limitation, if  
4           that makes sense.

5           I'm not aware of a single case that makes this  
6           distinction that if you have the antecedent reference in the  
7           dependent claim, that you just disregard it because it's not  
8           in the independent claim. That I believe fails as a matter  
9           of patent law.

10          We cited multiple, multiple cases where there is  
11          antecedent basis. That is a reason to find that the  
12          preamble is limiting, and I think Your Honor noted, the only  
13          case they have where there's this issue, the only case they  
14          cite to suggest that the preamble is not limiting is this  
15          weird outlier case where the parties specifically didn't  
16          argue that there was antecedent basis. And so we see an  
17          outlier decision there, but it wasn't even argued in that  
18          case. Here, we certainly are arguing it and it's nothing  
19          that we have for every patent.

20          So the other reason I would cite as to why the  
21          preambles are limitations, and if we go to our slide 38, it  
22          is because they do breathe life and meaning into the claim.

23          We heard Bio-Rad's counsel suggest that somehow  
24          GE, the patentee, didn't think that that was part of the  
25          invention and had some reference about liquid chromatography

1 systems in the prior art, but when we read the  
2 specification, it's abundantly clear that GE considered the  
3 invention to be very specific configurations of liquid  
4 chromatography systems.

5 And if we look at some of the excerpts we have  
6 here about Figure 2 and Figure 1 on the slide, the  
7 specification specifically refers to embodiments of the  
8 invention in the form of modular liquid chromatography  
9 systems. So there's ample evidence here that the patentee  
10 considered that to be structural limitations, structural  
11 requirements of the claim.

12 THE COURT: All right. So I agree with you,  
13 that's exactly what the patentee was doing, and it recited a  
14 particular structure in the written description. It  
15 highlighted that structure as important and that the  
16 preamble is limiting. It provides an antecedent basis for  
17 at least one claim in each of the asserted patents, and as I  
18 say, there are multiple instances where the written  
19 description cites a liquid chromatography system as an  
20 example of a fluid handling system. And the bottom line is,  
21 I do think it gives life, meaning and vitality to the  
22 claims. I don't think Summit is applicable. The parties  
23 weren't arguing an antecedent basis and I just don't find  
24 that as informative for my decision here. So the preamble  
25 is limiting I find.

1 All right. Let's move to the next term or set  
2 of terms, which is the liquid chromatography system and the  
3 automated liquid chromatography system. Let's hear from the  
4 plaintiff first.

5 MS. SKLENAR: Thank you, Your Honor. So if we  
6 turn now to slide 49, we see the parties' different  
7 constructions. And what we have -- I mean, it's basically  
8 similar to a plain and ordinary meaning construction. It's  
9 a system capable of performing liquid or automated  
10 chromatography given the particular wording of the claim.

11 And where do we get our construction from? Ours  
12 comes, and if we look at slide 50, from the Patent Office.  
13 That's what, in the PTAB decision, that's what, if you  
14 follow the rationale, their decision, the part of the claim  
15 that was being construed was liquid chromatography system.  
16 That is where the Patent Office explained what it means.

17 The construction that Bio-Rad --

18 THE COURT: Why do you want me to start looking  
19 at this IPR which uses a different standard. Right? I  
20 mean, why should I just cloud this up by making reference to  
21 the IPR?

22 MS. SKLENAR: Your Honor can do it or can't do  
23 it. I think for the preamble, there's a different  
24 situation, which we don't need to get into about why it's so  
25 relevant. For this, I think it is an example. You know,

1 it's persuasive authority that the Court can look to as to  
2 how the PTAB construed that language. But basically we just  
3 want it to be a system that does liquid chromatography. And  
4 if we look at Bio-Rad's construction -- I don't even know  
5 frankly that Your Honor needs to construe this, but if we  
6 look at Bio-Rad's construction, we don't really know where  
7 they're getting that construction from. It's different than  
8 what they asserted at the Patent Office.

9 If we look at their brief, we don't really  
10 know -- they don't seem to be arguing it based on a  
11 definition or some clear requirement in the spec. What they  
12 say in the first brief is that when they looked at a claim,  
13 that was the minimum requirement for a certain claim, but  
14 they cite no law that that is the way claim construction  
15 should be done. They don't have a declaration from somebody  
16 skilled in the art saying, this is the way everyone in the  
17 field at the relevant time would have understood these terms  
18 to mean.

19 So there's just really no meaning that they give  
20 or no support that they give to their construction. And  
21 what I think they are trying to do here is just give a vague  
22 enough construction that they basically can turn around and  
23 say, any fluid handling system that you could somehow modify  
24 to deal with the chromatography could be characterized as a  
25 liquid chromatography system. In other words, if you have a

1 water cooler, arguably, under Bio-Rad's construction, that  
2 would be a liquid chromatography system because you could  
3 somehow modify it and do what Bio-Rad replaced there, and we  
4 just don't agree that that is what someone skilled in the  
5 art would think a liquid chromatography system is. They  
6 have not supported it. We think other things would be  
7 required like detectors.

8 But I don't know that we need to get into any of  
9 that, because I think we should either -- we would submit  
10 that the Court should either give it its plain and ordinary  
11 meaning with no construction or adopt the one we have, which  
12 is basically just sort of explaining how that term would be  
13 understood, that it would be capable of. In other words, it  
14 would have components, the system would have components that  
15 can perform that liquid chromatography.

16 THE COURT: What does automatic, or automated  
17 mean rather?

18 MS. SKLENAR: Automated would mean that  
19 there's -- not mechanical, electrical components that  
20 help govern the liquid chromatography aspect of it or  
21 control the liquid --

22 THE COURT: All right. How does that different  
23 then? How does the automated liquid chromatography system  
24 differ from the liquid chromatography system?

25 MS. SKLENAR: So long ago, potentially still



1     used today, are very old-fashioned kinds where you could use  
2     gravity, for example, to do some aspects of liquid  
3     chromatography. And so the automated is getting at the fact  
4     that you definitely need some automation there, some  
5     electrical components.

6             So with that, Your Honor, I think that really  
7     covers the argument. We think their construction is too  
8     broad and doesn't really get to the issue of what a liquid  
9     chromatography system is. They want it to be broad enough  
10    that they can later argue, well, you could have modified  
11    something to perform liquid chromatography by doing all of  
12    these things to it. Maybe that's enough. And this is  
13    something we did see in the Patent Office proceeding where  
14    they took a system that was clearly a liquid handling  
15    system, had nothing, no disclosure having to do with liquid  
16    chromatography and tried to argue, well, that could be a  
17    liquid chromatography system because you can modify it, and  
18    the Patent Office rejected that, and that's the reason that  
19    the IPR wasn't instituted on certain of the claims.

20            THE COURT: So why didn't the patentee then, you  
21    know, title this patent and ask for patents in the abstract?  
22    Why didn't he just talk about a liquid chromatography system  
23    as opposed to an automated fluid handling system?

24            MS. SKLENAR: So as is typical in drafting  
25    claims, people, patent prosecutors will go generic and then

1 go narrower, and that's what's described in the spec. It  
2 talks about fluid handling systems, but then it talks about  
3 very specific types of liquid chromatography. And, in fact,  
4 in the parent patent, in the '718 patent, there were claims  
5 originally recited to both, and I think I have a slide that  
6 shows that similar to what we see on page number 47.

7 So what we see there are the claims that appear  
8 in the reissue patent, and this shows how they were affected  
9 from the IPR proceedings.

10 The claim we see on the left, that one was held  
11 to be unpatentable in the IPR proceedings.

12 THE COURT: What slide are you on?

13 MS. SKLENAR: 47.

14 THE COURT: Okay.

15 MS. SKLENAR: That was held to be unpatentable.  
16 The claim on the right, and, again, this is now part of the  
17 '124 reissue patent, that was the claim where the Patent  
18 Office refused to grant institution. Bio-Rad did not even  
19 get over the threshold of having this claim reviewed.

20 So we see that the patentee did try to write  
21 claims to both, and after the IPR decision, in prosecuting  
22 all of the remaining continuation patents, the other patents  
23 asserted in this case, we took, we basically took what the  
24 PTAB said to heart, that we weren't entitled to broader  
25 claims and limited all of the claims from then on to liquid

1 chromatography systems.

2 THE COURT: Okay. All right. Let me hear from  
3 the other side. Thank you.

4 MR. CORREDOR: Your Honor, if it please the  
5 Court, Felipe Corredor again for Bio-Rad.

6 I still -- I think we still have not heard from  
7 plaintiffs what the structure is that makes up the liquid  
8 chromatography system, and I think what we see here, if we  
9 don't have a structure, then it's just a statement of use.

10 And if we look at our slide 39, we have a  
11 citation to the Hewlett-Packard case in which the Federal  
12 Circuit held that apparatus claims cover what a device is,  
13 not what a device does. So it's very important that we,  
14 that these terms be structural. Because they are not, I  
15 think our position that they are mere statements of use and  
16 they have not pointed, the other side also hasn't pointed to  
17 anything structural that is inherent to liquid  
18 chromatography, and they still haven't in today's  
19 presentation. And so these statements of use could not be  
20 held to be limiting.

21 There's another case on the next slide, slide  
22 40, which makes the same point, and I think In re Schrieber.  
23 In that case, there was a dispensing top for passing popped  
24 corn, and as you see it highlighted in the claims here, a  
25 the lot the language had to do with popcorn. So a

1 dispensing top for passing only several kernels of popped  
2 popcorn at a time. And the element, the opening at the  
3 reduced end allows several kernels of popped popcorn to pass  
4 through at the same time, and so forth.

5 So there's a lot of limitations having to do  
6 with popcorn, and the Federal Circuit nevertheless held that  
7 in a reference that that had nothing to do with popcorn, a  
8 prior art reference that was related to the oil, so  
9 anticipated as a matter of under Section 102 that the claims  
10 at issue here and In re Schrieber, showing that the popcorn,  
11 the recitations of popcorn were mere statements of use that  
12 would not limit the claim.

13 THE COURT: Okay. But, wait. Didn't we already  
14 address whether it's limiting or not?

15 MR. CORREDOR: The process of the preamble.  
16 Sure, but I think we contend as well as to the extent it's  
17 also in the body, it should not be limiting, and I think  
18 based on Your Honor's ruling in the preamble, you might be  
19 inclined to find these are limiting. But to the extent they  
20 are limiting, I think the structural point is still an  
21 important one, so it's still important to keep in mind these  
22 cases, this case law in terms of if it's limiting, the  
23 proposed construction should be something that provides  
24 structure to whatever that term is, and I think that is why  
25 our proposed construction, we cite components, because GCS's

1 proposal, which is just a system capable of performing  
2 liquids chromatography, doesn't -- there's no structural  
3 component to it. I think it would be indefinite if the  
4 claim recited that alone, and so we really, the proposal we  
5 put forth if this is to be limiting is that there be  
6 specific components that are capable and that they can  
7 deliver with liquid chromatography.

8 So we're trying to give structural meaning to  
9 these terms, which I think we submit are not structural at  
10 all, but to the extent we have found that they are, the  
11 proposed construction should provide the structure that  
12 plaintiffs have not been able to point to.

13 THE COURT: So I guess I'm confused. I'm sorry.  
14 I understand those are arguments, I get them insofar as they  
15 relate to what I thought I already decided, which is whether  
16 the preamble is limiting or not. And, look, I've got to  
17 tell you, to be quite honest with you, I think the limiting  
18 preamble issue is one, it's very difficult. It's hard to  
19 reconcile how statement of purpose is not limiting, but a  
20 preamble is limiting if it gives meaning to the claim, but  
21 the Federal Circuit case law has both of those statements in  
22 it, so I'm never sure I get right whether a preamble is  
23 limiting. But I've decided it.

24 So I'm trying to figure out now the difference  
25 between the proposed constructions of each side and I'm not

1 really getting why the argument you've just made, is  
2 probative as it might be towards the limiting question or  
3 not, helps me decide whether I should construe a liquid  
4 chromatography system as either "a system capable of  
5 performing liquid chromatography" or "a fluid handling  
6 system that has components that can deliver controlled fluid  
7 flow through a liquid chromatography column."

8 You are saying that -- maybe I guess you're  
9 saying this column we need to provide the necessary  
10 structure to understand the claim? Is that your point?

11 MR. CORREDOR: Yes. I think the point is a  
12 structural one. So I think the plaintiffs' proposal still  
13 lacks structure. That's not an adequate -- I mean, if we're  
14 going to find the term limiting, which Your Honor has, then  
15 it could be a term that connotes structure and our proposed  
16 construction points to components that can deliver through  
17 the column. That is the structure we are trying to provide  
18 and I think that's the first point.

19 THE COURT: I guess why does it have to contain  
20 structure? Why can't it contain a use? I mean, I thought  
21 the use question comes up in terms of whether it's limiting  
22 or not, but if it is limiting, why then can't it be used  
23 space and basically recite what GE proposes, which it just,  
24 it limits the claim to be directed towards a system that's  
25 capable of performing liquid chromatography?

1 MR. CORREDOR: I think the reason is that if it  
2 is limiting, it can only be limiting if it's a structural  
3 component. Right? Because we are, especially with these  
4 systems, we are dealing with system claims, and  
5 Hewlett-Packard and Schreiber teach that these cannot be  
6 limiting.

7 So the fact that Your Honor has found these to  
8 be limiting means that they have to have structure because  
9 otherwise they would not have been limiting. I think that's  
10 why we submit that the proposed construction still has to  
11 have structure, and the case law that is relevant to whether  
12 it is limiting or not is also relevant to what the  
13 construction should be. That is, there should be a  
14 structural construction, not a mere statement of use.

15 And another point I want to make in favor of our  
16 proposed construction, I think it's illustrated on slide 41  
17 of our presentation, which has to do with their proposed  
18 construction, really renders a lot of language in the claim,  
19 in claim 38 of the '124 patent superfluous.

20 So if we're construing a liquid chromatography  
21 system as "a system capable of performing liquid  
22 chromatography," then we're rendering the bulk of the last  
23 limitation highlighted on slide 41, wherein the system is  
24 capable of performing liquid chromatography, we're rendering  
25 the bulk of that language totally superfluous.

1 And --

2 THE COURT: Well, but their point is that it's  
3 automated. I mean, automated is narrower than just a liquid  
4 chromatography system. I mean, you can have systems that  
5 gravity works as opposed to electric components and that's  
6 why you can actually have something. I guess you can have a  
7 non-automated liquid chromatography system.

8 MR. CORREDOR: Yes, but if the point was only  
9 automated, you wouldn't have -- they wouldn't have had to  
10 recite the capable of performing liquid chromatography  
11 portion of the language. So it's still rendering all of  
12 that portion superfluous.

13 They could have said when the system is  
14 automated, that is really where --

15 THE COURT: Well, they could have said that. If  
16 I read it in its totality, the clause still has some meaning  
17 because it has got the word automated.

18 MR. CORREDOR: Yes, but not all the terms of the  
19 claim have meaning, and I think if I read you a quick quote  
20 from Merck on page I guess 395 F.3d at page 1372, the  
21 Federal Circuit stated that a claim construction that gives  
22 meaning to all the claims it prefers over one that does not  
23 do so, and so the proposed construction that they're  
24 advocating reads out a lot of these terms.

25 You are right, it does not read out automated,



1 but it reads out a whole bunch of other terms. I think  
2 that's another reason why the proposed construction is  
3 wrong.

4 And, third, I think I heard plaintiff, there's  
5 no portion in the spec that discusses anything about the  
6 structure, and I think I would direct you to slide 42, which  
7 is a place where there is some structure discussed, what a  
8 liquid chromatography has. And so it states, and I will  
9 read it, "According to another embodiment, there is provided  
10 a fluid handling system in the form of a liquid  
11 chromatography system comprising a housing, two or more high  
12 pressure pumps, at least one sensor unit and a plurality of  
13 fluid control valves of at least two different  
14 configurations."

15 So there are components and these are the  
16 components that are referred to in our proposed  
17 construction, and these are special pieces that I guess make  
18 up the liquid chromatography system according to the  
19 specification.

20 I think that is the third and last point I would  
21 submit in favor of Bio-Rad's proposed construction for this  
22 term, assuming it is a limiting term.

23 THE COURT: All right. Thank you. I am though  
24 going to give it the plain and ordinary meaning, and I don't  
25 think it renders claim 38, the wherein clause of the '128

1 patent, superfluous. As I say, I'm not sure I got it right  
2 on the limiting issue, but you always have the Federal  
3 Circuit to correct things.

4 Okay. Let's go with the last set of terms,  
5 which is the fluidics and non-fluidics sections. Let's hear  
6 from the plaintiff first.

7 MR. MILLER: Thank you, Your Honor. This is  
8 Jeffrey Miller again.

9 And I'd like to direct your attention to slide  
10 58 of our slide deck. And this slide presents each side's  
11 proposed constructions, and it highlights the accused. And  
12 real, the main issue is in that second bullet point, which  
13 is whether the non-fluidics section requires all of the  
14 electrical components of a particular fluid handling unit.  
15 That's what Bio-Rad's construction would require. We think  
16 that that is unduly limiting.

17 THE COURT: But let me ask you, can I just ask  
18 something here? Hold on. You agree that the non-fluidics  
19 section cannot have fluidics components. Is that right?

20 MR. MILLER: That's right, Your Honor.

21 THE COURT: Do you agree that the fluidics  
22 section cannot have non-fluidics components in it?

23 MR. MILLER: It has a double negative in there.  
24 I need to think about that clearly. Cannot have  
25 non-fluidics.

1 I'm sorry. The question was: Can the fluidics  
2 section not have non-fluidics?

3 THE COURT: So, in other words, your position is  
4 for sure you're saying, hey, look, the non-fluidics section  
5 can't have fluidics components. Right?

6 MR. MILLER: Right.

7 THE COURT: So then let's do the flip side. Can  
8 the fluidics section have non-fluidics components?

9 MR. MILLER: Yes, it can, and --

10 THE COURT: Okay. That seems problematic for  
11 me. I thought you might say that the non-fluidics  
12 components can be external to the non-fluidics section and  
13 they can be external to the fluidics section, but you're  
14 telling me, so you're not treating them equally then.

15 MR. MILLER: Our -- so I think that what the  
16 claim says and what the specification says is that the  
17 non-fluidics section cannot have fluidics. I mean, that's  
18 what the non-fluidics says.

19 The fluidics section can have fluidics  
20 components for sure, and the specification plainly  
21 shows that there are things that are on the non-fluidics  
22 side --

23 THE COURT: Yes, but you say in your slide, "as  
24 evident by the phrase itself, the non-fluidics section  
25 cannot have any fluidics components in it." That's your

1 slide.

2 So why shouldn't the second bullet point read,  
3 "as evident by the phrase itself, the fluidics section  
4 cannot have any non-fluidic components in it"?

5 MR. MILLER: Because there's no negative  
6 language there. It would be inconsistent with the patent  
7 itself to say that. The patent literally discloses fluid  
8 handling units that have electrical components on the  
9 website, on the fluidics section. In other words,  
10 non-fluidics, it's pretty clear. It says non. It's a  
11 negative.

12 THE COURT: It says fluidics. I mean, you know,  
13 I kind of lose you there.

14 MR. MILLER: Well, the fluidics -- I mean, I  
15 will give you a perfect example.

16 So if you look at -- we'll probably talk about  
17 the pH electrode, but there are other examples.

18 THE COURT: Look, I think the pH electrode is a  
19 pretty good argument.

20 MR. MILLER: Yes.

21 THE COURT: I was thrown by your slide. You  
22 say, "as evident by the phrase itself." So if the phrase  
23 itself, non-fluidics means, as you say, that the section  
24 can't have fluidics, then the phrase fluidics seems to me  
25 would say, oh, if I use the same logic that it's the phrase

1       that is dispositive. Well, if the phrase is as you say on  
2       slide 66, as evident by the phrase itself, the non-fluidics  
3       section can't have fluidics components, I don't understand  
4       from that why the phrase fluidics section can have  
5       non-fluidic components.

6               MR. MILLER: Well, so non-fluidics has a -- I'm  
7       sorry. I'm not an English major. Non is negative, so  
8       that's clear. Right? You can't have any non-fluidics --  
9       I'm sorry, fluidics in the non-fluidics section.

10              THE COURT: Okay.

11              MR. MILLER: Fluidics though, it certainly  
12       requires that there be fluidics on that side.

13              THE COURT: Right.

14              MR. MILLER: It says nothing about it. It  
15       doesn't say you can't have them.

16              THE COURT: Okay.

17              MR. MILLER: Especially in the patent itself,  
18       which points out numerous examples of there being  
19       electronics on the fluidics side.

20              THE COURT: Okay. All right. Keep going.

21              MR. MILLER: Okay. So we had mentioned the pH  
22       electrode. I think you understand that, but if you go to  
23       slide 63, we've laid out one example of how that works. So  
24       if you look at claim 1 of -- this is the '591 patent, it  
25       talks about there being an external fluidics section of a

1 particular fluid handling unit. It qualifies it as a pH  
2 electrode that's external to the housing, and claim 26 says  
3 there's a pH electrode connected to the pH valve formed in  
4 an interchangeable modular component.

5 So that plainly demonstrates that there's at  
6 least two dependent claims that talk about there being a pH  
7 electrode, which there's no dispute that's an electronic  
8 component on the external portion of the fluid handling  
9 unit.

10 And if you look at the specification, if you  
11 look at slide 64, we've got a little piece --

12 THE COURT: You broke off. Your connection is  
13 very, very bad and now you broke off completely.

14 MR. MILLER: Can you hear me now?

15 THE COURT: Yes.

16 MR. MILLER: Okay.

17 THE COURT: Can I just say something to counsel?  
18 I mean, you all have got to do something better. Now we're  
19 all I know dealing with this pandemic and we're having to do  
20 things by phone. The number of times that folks do not have  
21 a good line, it's frankly really concerning.

22 So especially to the Delaware counsel on the  
23 line, please get the word around. I mean, on pretty much  
24 every call there's at least two lawyers that have a problem  
25 with their connection. They need to check it out ahead of

1 time. It's really hard for our court reporter to do all of  
2 this.

3 MR. MILLER: Your Honor, I really apologize for  
4 that. Actually, I was pretty confident that it was working  
5 well because everyone that I've spoken to on this system has  
6 never complained, but I guess my indirect connection must be  
7 degraded today.

8 But anyway, so I want to go back to what I was  
9 talking about with respect to slide 64. We've got the  
10 little piece of column 4 there, but I actually think if you  
11 look at the entire paragraph, which is in the '589 patent,  
12 it starts at line 45 of column 4, and we referred to the  
13 first three lines of this. But if you go through the entire  
14 paragraph, it really enforces that this is an electrical  
15 component that is on the external portion of the fluid  
16 handling unit.

17 And it says that, it talks about flow  
18 restrictor, which is that's not an electrical component, is  
19 connected to the pH valve, and then it goes on and it says,  
20 the pH valve is used to direct the flow, and that's the  
21 fluid, the flow to the pH electrode and to the flow  
22 restrictor or to bypass or both.

23 So it's plainly teaching that there's a pH  
24 electrode that's part of the fluid modular, modular fluid  
25 handling unit that's in the fluidics section.

1           So, and I think it's important to look at a  
2   couple of more pieces of the specification, and I will  
3   direct your attention to slide 67. Here we are talking  
4   about, pointing out a quote from the '589 patent, which is  
5   column 6, lines 3 through 13. We highlighted in yellow a  
6   portion of it.

7           It says, according to one embodiment, the panel  
8   member, which is a part of the fluid handling unit,  
9   essentially separates the fluidics and the external fluidics  
10  section from electronics and control means in the internal  
11  fluid non-fluidics section.

12          So what that is saying is that the panel member  
13  separates the external fluidics section from whatever  
14  electronics happen to be in the, in the non-fluidics  
15  section. It doesn't say anything about all of the  
16  electronics have to be there, and, again, that would be  
17  inconsistent with all the embodiments, which talk about  
18  having electronics in that fluidics section.

19          The next slide 68 refers to another portion of  
20  the specification. And you can see about a third of the way  
21  down, it says, said panel attachment member may, so this is  
22  just one possibility of the embodiment, may be arranged so  
23  that "all," the word "all" is there, "fluid connections of  
24  the said modular component are arranged on a wet side panel  
25  of the attachment member."



1           It says, separating them from, and notice the  
2 word "all" is not there, all electrical components are  
3 working on the dry side. So this again is reinforcing  
4 what we've been saying, which is that, yes, there are only  
5 going to be electronic components in this, in the fluidics  
6 section -- not fluidics section, excuse me, but it doesn't  
7 say anything about all the electronics of the system having  
8 to be in that non-fluidics section.

9           Now, again, slide 69, this is just another  
10 example from the specification. It talks about there being  
11 sensors at the liquid handling panel. That's the external  
12 piece there. That's an electronic component. It's in the  
13 slide, but I didn't mention it yet.

14           So slide 65. That's Figure 2 which we talked  
15 about earlier. You can see a number of those components,  
16 like the column valve, the pressure sensor, pressure sensor,  
17 electrical component. Those are all the other sensors that  
18 are located. Those are electrical components that are in  
19 the fluidics section.

20           So I wanted to briefly address the prosecution  
21 history and then I will turn it over or answer any questions  
22 you have.

23           So here, Bio-Rad is arguing that there has been  
24 a clear and unmistakable disavowal of claim scope, and we've  
25 been through all of their quotes and whatnot from the

1 specification, and we don't think that a company, we're  
2 close to being clear disavowal.

3 And if you look at slide 72 of our slide deck,  
4 you can see that there are two excerpts from the Mourtada  
5 reference, which is where the bulk of the discussion took  
6 place. These two portions of the figure, they were  
7 reproduced in both an office action response and Bio-Rad  
8 reproduced them in one of their briefs as well. And what  
9 they showed, that there is no non-fluidics section in  
10 Mourtada, and that's true also for Bergstrom and for Hess.

11 This was the point that was made over and over  
12 again during prosecution by the patent attorney, which is  
13 that there is no non-fluidics section in this prior art.  
14 And you can see that clearly in Mourtada because there's  
15 this barrier, there's this wall where it is installed into.

16 And on one side, and you can see that on the  
17 left-hand side of the slide, there are components and then  
18 there's some tubing, which is labeled as 104, and if you  
19 look at the right-hand side, there's also tubing, and what  
20 is shown there is there's a pump right below that or below  
21 and to the left. And the point is, is that they HAD  
22 distinguished this prior art and all the other prior art  
23 and said, look, the electrical components and whatnot and  
24 the fluid stuff, there's no non-fluidics section at all, so  
25 therefore you can't say, you can't disallow this claim

1 over this prior art. That point was made over and over  
2 again.

3 We put one example in here, so on slide 73.  
4 This is in the September 2013 office action response.  
5 There's a quote and it says, thus, even if the valves, et  
6 cetera, 105 and 203 were considered to be modular, there  
7 were respective fluidics sections on both sides of those  
8 cassettes. In other words, the patentee was saying here and  
9 they said it over and over again that there is no  
10 non-fluidics section in this prior art and that's the key  
11 piece.

12 Now, I'm sure when Bio-Rad comes up, because I  
13 see it in their slides, they're going to be talking about  
14 all of this discussion about electrical components and this,  
15 that and the other thing. But there's an important proviso  
16 to that, which is that the claims that we're painting when  
17 those arguments were made specifically said that the  
18 non-fluidics section in term comprise electronics or  
19 electrical components or control means. We've reproduced  
20 that claim in slide 74. So it's not at all surprising  
21 that the words electrical components and whatnot were  
22 used.

23 But I would submit, Your Honor, that there's  
24 nothing about claim 16 or any other claims that even where  
25 they recite an electrical component in the claim language

1       regarding the non-fluidics section, it doesn't say anything  
2       about the preclusion of any electronic components in the  
3       fluidics section, and, again, that would be completely  
4       inconsistent with what the patent teaches.

5               So we would submit, Your Honor, that there has  
6       been no disavowal. I think that sums up our argument. Do  
7       you have any questions for us?

8               THE COURT: Yes. Where are you calling from?

9               MR. MILLER: I'm in California.

10              THE COURT: And why are you using an Internet  
11       phone?

12              MR. MILLER: Because that's the only phone I  
13       have.

14              THE COURT: All right. Let me hear from the  
15       other side.

16              MR. BILSKER: Good morning, Your Honor. It's  
17       David Bilsker for Bio-Rad.

18              I want to address some of the things that you  
19       first raised. One of the first points that you made was you  
20       asked plaintiff why you're not treating equally the fluidics  
21       and non-fluidics side and you said that was problematic. I  
22       agree.

23              What they are saying is, if electronics get wet  
24       on one side, it's a problem, but if electronics gets wet on  
25       another side, it's not a problem. That doesn't make any

1 sense. Wet electronics are a problem whether they're on one  
2 side or the other. If electronics are on one side and they  
3 get wet and they are part of the module, well, that  
4 electronic system is not just isolated completely on the  
5 outside. It goes to the inside as well. That's where other  
6 portions -- I mean, GE admits that there has to be  
7 electronics on the inside, and it is the electronics on the  
8 inside that then connect to the buff and all of those things  
9 which are taught in the patent. If I short out my  
10 electronics on the outside, that short is also going to  
11 carry through to the electronics on the inside.

12 THE COURT: All right. Don't you agree that  
13 there's an embodiment in the written description which has a  
14 pH electrode that is external to the housing?

15 MR. BILSKER: There is a pH electrode which is  
16 external to the housing, but that pH electrode is not part  
17 of the module, and let me just go to our slides on that.  
18 Sorry. I've got to scroll to which slide it is.

19 All right. So starting at our slide No. 62, if  
20 Your Honor is there yet?

21 THE COURT: Yes. Okay.

22 MR. BILSKER: All right. So in the  
23 specification it says, you've got a pH valve. Right? And  
24 when look at the figure, Figure 2, the pH valve is what is  
25 identified.

1           Now, on the pH valve, there is maybe -- there's  
2   a little cup or reservoir, if you will, and in that cup or  
3   reservoir one may install or connect a pH electrode to it.  
4   It does not say the pH electrode is an integral part of the  
5   actual pH valve module. The pH, the electrode can be hooked  
6   up to a separate monitor, like a separate computer or a  
7   separate device, and it can be dipped into the reservoir on  
8   the module itself.

9           So let's say that that electronic thing, that  
10   electrode gets screwed up and it gets short out because it's  
11   wet. Does that travel back to the electronic in the module?  
12   No. And that's why you see in every single one of the  
13   citations that they made, they actually, they actually  
14   support it.

15           If you go to slide 65 where they cited some of  
16   the claims that recited the pH electrode. So it's  
17   interesting to see that it never says the pH electrode is  
18   part of the module. It says it's part of the system. And  
19   there's actually, there are actually in that claim 12 that  
20   we've got shown up there on slide 65, it actually says the  
21   pH electrode is external to the housing. It doesn't say  
22   part of it. It says all of it.

23           Now, if the pH electrode was part of the module,  
24   the only way to communicate in any kind of electrical way  
25   is, it would have to be connected to the electronics in the

1 module, but this thing says the entire pH electrode is  
2 external. So that supports us. So does claim 26. It says,  
3 the electrode is connected to a valve. It doesn't say it's  
4 part of the valve. And we've cited, I believe it's in the  
5 next slide, a number of cases from the Federal Circuit which  
6 says when A is connected to or attached to B, they're not  
7 the same thing. So the electrode connected or attached to  
8 the pH valve, which is a totally separate thing, is not the  
9 pH valve, and the pH valve is what the module is.

10 Now, you know, I think one of the other -- so I  
11 think I've addressed the pH electrode specifically with  
12 respect to the specification, but when I get into the file  
13 history, you're going to see that it absolutely, the  
14 electronics cannot be on the outside. The electronics of a  
15 module cannot be on the outside. That's not to say in the  
16 system overall there can't be an electrical part which is  
17 part of the system on the outside.

18 And, you know, just to address, and you can tell  
19 me to shut up and move on, but this non-argument, the one  
20 where non-fluidics means you can't have any fluidics, but  
21 because the word non is not in the fluidics, you can have  
22 electronics.

23 I mean, I think I have a slide and I took it  
24 out. It's kind of like the chicken and the egg. Had we  
25 called it electronics, then we would have called the other

1 side the non-electronics. I mean, they took the word and  
2 called the other side the non and, you know, one of the  
3 things that plaintiff said was, in all the file history  
4 stuff you can disregard it because the claims that were at  
5 issue on the non-fluidics, we're talking about electrical  
6 components specifically, I have no idea what relevance that  
7 has to the issue because everyone agrees that non-fluidics  
8 means exactly the same thing in all of the patents.

9 So when they were talking about electronics in  
10 those claims, and the reason they were talking about  
11 electronics, we think because they are part of the file  
12 history. It's not in your briefing because this is kind of  
13 a new argument. But the reason non- -- in the original  
14 claims when it said non-fluidics, they had to specify  
15 electronic components. Just because they got a 112  
16 rejection where the Examiner said, well, what does  
17 non-fluidics mean? I mean, that could be a solvent. You  
18 know, like the knobs. Those are non-fluidics.

19 So what do you mean by non-fluidics? And they  
20 had to, they had to amend the claim to say, by non-fluidics,  
21 we mean electrical stuff, and that's what it means  
22 throughout all the claims.

23 And --

24 THE COURT: And I realize, you know -- well, can  
25 I see that? Is that somewhere in the record before me in



1 the written brief?

2 MR. BILSKER: It is not in the record. What you  
3 can see in Exhibit G, which is kind of like the one exhibit  
4 that I'm going to point to over and over again, in Exhibit G  
5 at page 1465, you will see the amendment, but I don't  
6 believe that anyone put in the rejection that said you need  
7 to tell me what non-fluidics means and then that's why they  
8 added that in. But, again, Your Honor, I don't think  
9 there's any disagreement when we say non-fluidics, it means  
10 exactly the same thing in all of the claims.

11 So the fact that they were talking about  
12 electronics in the original prosecution when they were  
13 referring to non-fluidics, I don't think that means that  
14 somehow electronics are excluded in all the other claims  
15 that say non-fluidics. That really wouldn't make sense.

16 We can supplement the record if you want to try  
17 to find -- well, I know we can find the original rejection  
18 that rejected it on the 112 grounds, and I just happen to  
19 remember that from long ago. But I'm positive we didn't --

20 THE COURT: Let me hear from the plaintiff. I  
21 think they would probably be well advised to agree with you  
22 on that.

23 Do you agree, plaintiff, that non-fluidic is  
24 synonymous with electrical? Is that right?

25 MR. MILLER: Yes, that's right. I mean, it

1       could be more than that.

2               THE COURT: On page 73 of the joint claim brief  
3       you've got a parenthetical which says, "which has  
4       non-fluidic or electrical component" when you refer to the  
5       pH electrode. So I'm going to assume then based on that and  
6       your answer, which is a candid one, I think, yes, they are  
7       interchangeable, to use a word we've used. So, okay.

8               All right. So keep going then, Bio-Rad.

9               MR. BILSKER: It's Mr. Bilsker again.

10              So I did address the pH electrode. You did hear  
11      from plaintiff throwing out this argument that, oh, and  
12      there's a bunch of other electrical components that are part  
13      of modules and that are on the outside.

14              There is no evidence that those other things  
15      that they identify are electronic. For example, a pressure  
16      sensor. Are they telling us that no one ever measured  
17      pressure until we got into the digital age and had an  
18      electronic pressure measurement? I think even from common  
19      experience, we recognize that's not the case.

20              Every time we go to the gas station and our  
21      tires are a little low and we go to fill it out and we take  
22      out our trusted little, you know, tube device that fits on  
23      the air nozzle and push it down and look at what the  
24      pressure is, you know what the pressure is. That is a  
25      pressure sensor. It has absolutely no electronic component

1 in it.

2 None of these things that they describe as being  
3 electronic are actually described in the specification as  
4 being electronic. So I will agree that an electrode, given  
5 the word electrode is electronic, but all the other, you  
6 know, the other components that they rely on that are  
7 electron I do not agree on and there's no evidence of that.

8 And --

9 THE COURT: Hold on. Give me a second to digest  
10 some of the things you've said. Hold on.

11 (Pause.)

12 THE COURT: I'm just taking time here because as  
13 I listen to the arguments, what just really calls out to me,  
14 I just wonder whether there's not something that both sides  
15 really should agree to here, that the --

16 MR. BILSKER: Well, Your Honor, it's David  
17 Bilsker.

18 I think both sides are in agreement that the  
19 non-fluidics side does not have any fluids or liquids on it,  
20 so the non-fluidics section cannot include any fluids or  
21 liquids. It's just the point that you raised, the first  
22 question you asked the plaintiff. We're not talking, you  
23 know, equality here on both sides.

24 So electronics can't get wet on one side, but  
25 they can get wet on the other, which I can tell you from

1 personal experience, having to use my cellphone right now,  
2 my gate in the front of my house is connected to my  
3 hardwired phone and it got wet outside and it shorted out  
4 everything in my house on my phone, so I'm on my cellphone  
5 now. And that's the same problem we have, as you say  
6 electronics can get wet on the outside of the system.

7 So I think that's the only thing we can agree  
8 to, Your Honor. I think we're in agreement that no fluids  
9 in the non-fluidics section, and I think we are arguing  
10 about what is in the fluidics section. Does the fluidics  
11 section allow electronics to get wet there? There's no  
12 problem, which Bio-Rad says no. He says yes.

13 Your Honor, may I proceed or do you still want  
14 time?

15 THE COURT: Hold on.

16 (Pause.)

17 THE COURT: Let's do this, Bio-Rad. Let's start  
18 with this. We've got an indefinite article here, which the  
19 Federal Circuit says that means one or more.

20 MR. BILSKER: Yes.

21 THE COURT: You're opening the door then to, and  
22 that it doesn't mean all.

23 MR. BILSKER: Well, I assume -- sorry. I assume  
24 you're referring to a section? Is that what you are  
25 referring to?

1 THE COURT: Yes, yes.

2 MR. BILSKER: Okay. I can certainly address  
3 that, Your Honor.

4 THE COURT: Okay. Go ahead.

5 MR. BILSKER: I think it begs the question, what  
6 is a section? Is a section any fluid component or any  
7 electrical component?

8 I think the argument is circular, that a  
9 fluidics section means any single component. If that's what  
10 it meant, it would have said, a fluidic component and/or a  
11 non-fluidic component, and I can absolutely show you as we  
12 go through the statements in the file history that that is  
13 not what a section means. A section, a fluidics section,  
14 means all of the fluidic components. A non-fluidic section  
15 means all of the electrical components. And absolutely I  
16 will show you that as I go through the file history.

17 May I proceed?

18 THE COURT: Yes, but I want you to do, and it's  
19 difficult with the telephone. I'm going to let you do the  
20 file history, but I want you to first walk me through your  
21 best argument based on the written description and do them  
22 in order of priority.

23 What's your number one piece of evidence in the  
24 intrinsic evidence, in other words, and I want you to  
25 prioritize written description over prosecution history. In

1 other words, you pointed me in the written description, I  
2 think, to compelling evidence that rebuts arguments made by  
3 GE, but as I sit here right now, I don't have in my brain  
4 where you pointed me to language which makes it clear why  
5 your construction is the right construction.

6 MR. BILSKER: Okay. So if we go to slide 50 of  
7 the Bio-Rad presentation.

8 THE COURT: Yes.

9 MR. BILSKER: And let me know when you are  
10 there. So slide 50 is an excerpt from column 6, lines 23 to  
11 35 of the '589, and it is talking about fluidics sections,  
12 non-fluidics sections. But what you will also see in there  
13 is that it says, it starts out, a panel member arranged to  
14 separate the fluidics section from the non-fluidics section,  
15 and then what does it go on to explain as to what those  
16 mean?

17 The panel member, it goes on, said panel  
18 attachment member may be arranged so that all fluid  
19 connections. So all fluid connections of a module is more  
20 than just one particular component. For example, a valve  
21 has, like, six or seven ports in it many times and many  
22 different tubes coming out of it. So if you were to say,  
23 well, the fluid section just means any one of those tubes,  
24 that would be inconsistent with the statement. It says, all  
25 fluid connections.

1           And then it goes on to say, are arranged on a  
2   wet side of the panel attachment member separating them from  
3   electrical components. It doesn't say one electrical  
4   component. It says, all electrical components of the  
5   module.

6           And, you know, I will agree that the  
7   specification is not explicit to say that every -- I think  
8   it was assumed just because given what the purpose of the  
9   invention was, which was to prevent electronics from getting  
10   wet, it was you need your electronics separated from your  
11   wet stuff, again, regardless of where they are.

12           I mean, again, it doesn't make sense for a  
13   person of ordinary skill in the art to say, well, you can  
14   get this electrical component wet and it will get screwed up  
15   and that's okay, but if this other one gets wet and gets  
16   screwed up, that's not okay.

17           So I don't think there's anything in the  
18   specification that says it's okay to screw up some  
19   electrical components with wet, but not other electrical  
20   components with wet on a module itself. And I apologize,  
21   Your Honor, but this does become crystal clear when you go  
22   to the file history.

23           THE COURT: Okay.

24           MR. BILSKER: So if that's okay, that's where  
25   I'm going to go now.

1 THE COURT: Yes. Let's go to the file history.

2 MR. BILSKER: So just as an overview, in slide  
3 54, we lay out the four things that the file history can  
4 show you and Your Honor can look at those.

5 It is going to show that a section doesn't just  
6 mean you can draw a circle around any one component and  
7 claim --

8 THE COURT: Wait. What did you say? You're on  
9 what right now? I couldn't hear.

10 MR. BILSKER: I'm on 54.

11 THE COURT: 54?

12 MR. BILSKER: Yes.

13 THE COURT: All right.

14 MR. BILSKER: So 54 is the five things that the  
15 file history is going to show you, and one of the most  
16 important ones is that a section, it's not just something  
17 that you can draw a circle around. You can pick one  
18 component, draw --

19 THE COURT: Hello? Hold on. Now you broke up.

20 MR. BILSKER: Can you hear me?

21 THE COURT: I can hear you now.

22 MR. BILSKER: Okay. Sorry. I feel like we're  
23 on that commercial.

24 So what I'm saying is, you can't just pick any  
25 individual component and then draw a circle around it and



1 say it's a section even though it's surrounded by a bunch of  
2 other different components on the same module of the same  
3 type. It's all of those are the same type that make up the  
4 section.

5 So in discussing the file history, I think one  
6 of the things that really stands out both in the argument  
7 and in the briefing is that GE really only addresses the  
8 Mourtada reference. They completely ignore the Bergstrom  
9 and the Hess discussion, and Bergstrom and Hess really do  
10 drive home the points that what we're talking about is all  
11 electrical components must be separated from all fluid  
12 components on a module, and that's, I mean, Hess makes it  
13 absolutely clear and so does Bergstrom.

14 If we go to Mourtada, you know, even if I was to  
15 concede that this is only talking about fluids going to the  
16 electrical side and not electric going to the fluid side,  
17 well, that does happen to be the situation that was  
18 illustrated in Mourtada, but I don't think there's anything  
19 about the discussion that says it's okay to get electronics  
20 wet when they are on the fluid side. It just happened to be  
21 the very specific thing that they were talking about in the  
22 Mourtada example.

23 And, you know, one thing that's interesting, if  
24 you go to slide 57, this is a diagram, this is the diagram  
25 that they were actually talking about. And on 57 you can

1 see in red, that's the 104 tubing that was going to the  
2 electrical side. You kind of see a little squiggle on the  
3 top left and top right that shows that going through the  
4 panel and onto the electrical side. But what you see in  
5 yellow is a bunch of other tubing that's fluidics.

6 And now, are we really -- I mean, is plaintiff  
7 really saying you draw a circle around the red thing and  
8 that's one section, and you draw another circle around, say,  
9 the yellow that's just below the red. That's another fluid  
10 section, and a circle around the other yellow, that's  
11 another one. That's just not how anyone talked about it.

12 If we go to slide 58, here's where we start  
13 getting into the other references. This is Bergstrom. And  
14 what you can see in Bergstrom is they got rejected over  
15 that. Applicant then came back and said, wait, wait, wait,  
16 wait. In Bergstrom, what's shown on the outside of one of  
17 these modules is a detector 40, and that detector has a  
18 processing unit 55, which they say is very likely to be  
19 electronic in nature. And they then say, well, that can't  
20 work because now you've got something electronic in nature,  
21 the processing unit of the detector, right next to liquids,  
22 and that is not going to work.

23 They say, you know, at the bottom there it says,  
24 liquids, liquid and electronic parts sit side by side, so  
25 they are not even using the word section there. They are

1 talking about parts even though the claims were directed to  
2 sections at that point.

3 If we go to the next slide, which is 59, and,  
4 I'm sorry. I'm just turning to my hard copy as well.

5 THE COURT: So you're saying liquid and  
6 electrical parts is side by side in Bergstrom. Right?

7 MR. BILSKER: Absolutely.

8 THE COURT: All right.

9 MR. BILSKER: They are saying they sit side by  
10 side in Bergstrom and therefore Bergstrom doesn't anticipate  
11 because in the claimed invention, fluidic and electronic  
12 parts, cannot sit side by side.

13 THE COURT: Right. Right.

14 MR. BILSKER: And slide 59, it's again, it's  
15 another discussion of Bergstrom, and it's not -- in  
16 Mourtada, the discussion was pretty limited. It was maybe  
17 two pages, but Bergstrom and Hess goes on through pages and  
18 pages and they repeat the same thing many times.

19 So in slide 59 it says, modules in Bergstrom do  
20 not separate their fluidic and electronic, electrical parts.  
21 Then if you go onto the next part that's highlighted, again,  
22 fluidic and electrical parts are not -- fluidic and  
23 non-fluidic parts are not separated. There's no suggestion  
24 that you separate those.

25 And then if we go to the next slide, then it

1 becomes even more clear that when you are defining a  
2 section, it's all the parts.

3 So this is Bergstrom yet again, and it's a  
4 little bit weird, Your Honor, and I'm not exactly sure how  
5 this happened, but in Exhibit G, if you go back to read it,  
6 the pages do not appear chronologically. It seems like they  
7 were reproduced, I don't know, in some weird order. So I'm  
8 just noting that for you, because when I looked through it,  
9 I had trouble finding the pages. They are not in numerical  
10 order.

11 THE COURT: Right.

12 MR. BILSKER: There's, like, three separate  
13 sections. But, in any event, in slide 60, what you see, it  
14 says, it is clear from Bergstrom that this plug-in system  
15 cannot separate fluidics and non-fluidic parts as claimed.  
16 Well, the claims didn't say anything about parts. It said  
17 sections.

18 And if you keep going on, again, it says, the  
19 fluidic and non-fluidic parts, I've underlined parts in red,  
20 and then here's the part that shows that they're equating  
21 all of the parts with a section. The fluidic and  
22 non-fluidic parts are separated by the panel member such  
23 that the respective fluidics sections of the fluid handling  
24 unit are external to the housing and the non and the  
25 respective non-fluidics sections are internal to the

1 housing.

2           So this is what the plaintiff is saying about  
3 the claimed invention. The sections are separated because  
4 all of their parts are separated. That's how they're  
5 interpreting their very own claim.

6           And then, so slide 61, which I don't really need  
7 to go through that much, but this is a figure of the  
8 detector in Bergstrom that they were talking about. Forty  
9 is the detector and 55 is the microprocessing unit they were  
10 talking about, and those are on the outside of the module,  
11 part of the module, integrated part of the module, and they  
12 said that doesn't work.

13           But here is the most, I think the most salient  
14 point, which was never addressed by GE and they completely  
15 ignored it in the briefing and here. This is the Hess  
16 reference. And in Hess, what the applicant said is he has  
17 these boxes, and the boxes were alleged to be the modules in  
18 the housing. And what the applicant said is, hey, the  
19 module in Hess, it has this electrical wire coming out of it  
20 and external to the housing. And they said, no, no, no.  
21 That can't be our invention because now you've got a  
22 non-fluidics part or section that is not internal to the  
23 housing.

24           So you heard plaintiff say, hey, everything in  
25 the file history just said there can't be fluid on the

1 non-fluid side. Well, here's the applicant during the  
2 argument, or during the prosecution saying, hey, you can't  
3 have non-fluidics or electronics on the fluid side. All of  
4 your non-fluidics have to be inside the housing. If you  
5 have a part of a module that has electronics on the outside  
6 where the fluidics are, that is not our invention.

7 So I think that that is the absolute most -- I  
8 mean, that is dead-on, and what plaintiffs are arguing is,  
9 hey, disregard it because it's not a clear disavowal. Well,  
10 I actually think it is a clear disavowal, but I also think  
11 one of the points they are making, I think it was their  
12 slide 21 and 22, when they were arguing about  
13 interchangeability. It's interesting that they said, well,  
14 when you look at the file history to interpret something  
15 when we want to interpret it, it doesn't have to be a clear  
16 disavowal because it's a coined term.

17 Well, fluidics section and non-fluidics sections  
18 in the context of the patent, are they standard everyday  
19 terms? I don't know. I guess we could argue about that. I  
20 don't think it's a term that people commonly use. I mean, I  
21 think you understand what it means, but, you know, I think  
22 the point about you need a clear disavowal for us, but you  
23 don't need it for them I don't think is justified, but even  
24 if it was, I think there is a clear disavowal when you look  
25 at them saying Hess is not our invention because as part of

1 the module, you have electronics on the outside.

2 And, you know, the rest of the slides, I don't  
3 know. We've already gone through the pH valve -- excuse me,  
4 the pH electrode. But, you know, if we go to slide 67, this  
5 actually goes back to the pH electrode, but I think Your  
6 Honor said you've already understood that, so you don't want  
7 me to go through this more.

8 But what this one said is, hey, all electronics  
9 that are, that are part of a system are not necessarily part  
10 of a module. And this is in a footnote in one of the  
11 discussions in Bergstrom, because the Examiner was trying to  
12 say, hey, this module has electronics, and plaintiff, or GE  
13 said, wait, wait, wait, wait, wait. There's electronics,  
14 but they are not part of the module. And I think that  
15 matches up perfectly with a pH electrode.

16 THE COURT: Okay.

17 MR. BILSKER: And you've got electronics outside  
18 as not part of the module.

19 And then the rest of the slides, 68 and 69,  
20 certainly, Your Honor can read those further. You know  
21 those cases. We've already cited them. I don't think I  
22 need to go through them.

23 And then 69 just goes through this issue where  
24 they say there's no clear disavowal, but they never  
25 addressed Hess, and Hess is a clear disavowal.

1 And I --

2 THE COURT: All right. Let me say this. I'm  
3 in your corner right now, so let's give the plaintiff a  
4 chance.

5 MR. BILSKER: All right. I guess you're saying  
6 rebuttal.

7 THE COURT: I'm sorry. What?

8 MR. BILSKER: You said let's give the plaintiff  
9 a chance.

10 THE COURT: To respond.

11 MR. BILSKER: Okay.

12 THE COURT: Let's hear -- all right. So let's  
13 hear from the plaintiff.

14 So let's start with the pH electrode. Okay? I  
15 came into this argument thinking I was going to rule your  
16 way pretty much based on that, but right now I'm persuaded  
17 that the valve and the electrode are two different things  
18 and they ought to be treated as two different parts.

19 So can you respond to that first? Hello?

20 MR. BILSKER: Mr. Bilsker is still on. I'm  
21 going to put myself on mute.

22 MR. MILLER: I'm sorry, Your Honor. I had  
23 myself on mute.

24 THE COURT: Okay.

25 MR. MILLER: Can you hear me now?



1 THE COURT: We can. Thanks. Go ahead.

2 MR. MILLER: Okay. Sorry about that.

3 Let me first point to Figure -- column 4. I  
4 mentioned this earlier, but this portion of the  
5 specification starting at line 45 talks about this pH  
6 electrode. It says that there's an integrated flow cell  
7 where the pH electrode can be installed, so there's this  
8 flow cell which is integrated into the module and the pH  
9 electrode is put in there.

10 So when you have a module that has, you know,  
11 for example, a little connection that is integrated into  
12 something and the pH electrode fits within it, that pretty  
13 clearly says that it's part of the module at that point. So  
14 that would be the first point.

15 And I would like to address this business about  
16 the pressure sensor and the valve and the tire gauge that  
17 Mr. Bilsker referred to. These patents, as we talked about  
18 earlier, are directed to automated liquid chromatography  
19 systems. These sensors are electronic. They are not like  
20 the tire valve. You need to have a sensor that gives a  
21 reading that can feed into an electronic system. So it's  
22 going to be an electronic device.

23 So there are numerous other embodiments in the  
24 patent that talk about having components on the wet side of  
25 the module, and, you know, we identified those sensors, but

1 if you look at the same portion of the patent, there's a UV  
2 monitor. Obviously, that's going to be electronic.

3 THE COURT: All right. So let's talk about the  
4 prosecution history then. I mean --

5 MR. MILLER: Okay.

6 THE COURT: -- I think Mr. Bilsker makes a  
7 compelling argument that looks pretty clearly and  
8 unequivocally, your client, or the applicant for the patent  
9 I should say made clear, clearly and unequivocally, as far  
10 as I'm concerned, that there are two sections, and that's  
11 what differentiates this patent from Bergstrom and Hess. So  
12 why don't you walk me through your response to that.

13 MR. MILLER: Okay. So, first of all, I think  
14 it's important to note that we don't disagree that there's  
15 going to be a separation from the fluidics section and  
16 non-fluidics section, but, first of all, there can be other  
17 sections.

18 As you pointed out, the claim language talks  
19 about a fluidics section and a non-fluidics section, and all  
20 the claims use the transitional phrase comprising, which  
21 means there can be other sections.

22 So even if you draw the circle --

23 THE COURT: That wasn't how you distinguished  
24 Bergstrom and Hess. I mean, you pretty explicitly said to  
25 the Examiner, hey, what makes this different is we've got

1 complete separation of the fluidic and the non-fluidic  
2 section. And, incidentally, I think that's consistent with,  
3 you know, your slide, which says, hey, the phrase itself  
4 tells you, there's no fluidic component in the non-fluidic  
5 section.

6 MR. MILLER: Well, our argument on non-fluidics  
7 in the fluidics section, that's what I called the  
8 non-fluidics section.

9 THE COURT: As opposed to the fluidics section.  
10 I mean, it's a referential definition. Right? It says,  
11 this is a non-fluidics section as opposed to the fluidics  
12 section.

13 MR. MILLER: Well, yes, but where is the  
14 negative language that says that there can't be? I would  
15 submit, Your Honor, that when it says fluidics, that just  
16 means there can be fluidics components. It doesn't say that  
17 there can't be anything else. There's going to be other  
18 things. There's going to be the pressure sensors, there's  
19 going to be the UV monitors. There's going to be all kinds  
20 of other things, and the patent explicitly teaches that.

21 So why don't you turn to the prosecution  
22 history.

23 So, first, let's talk about Bergstrom. We  
24 addressed Bergstrom in our brief, by the way. I'm not sure  
25 where they are coming from with that.

1 THE COURT: Where in your brief? Why don't you  
2 point to me in your brief where you address it.

3 MR. MILLER: One second, please. I need to find  
4 it. It's on page 867.

5 THE COURT: Okay. Go ahead.

6 MR. MILLER: So in Bergstrom, again, I'm looking  
7 at their slide 58.

8 THE COURT: Their slide? Okay.

9 MR. MILLER: Well, they have the Bergstrom slide  
10 here.

11 THE COURT: Yes.

12 MR. MILLER: This is distinct in Bergstrom.  
13 Again, it says the detector also includes a processing unit.  
14 This is actually an important point. Liquid chromatography  
15 systems have detectors in them.

16 As far as I know, every model of a liquid  
17 chromatography system has a detector in them and the  
18 detector is going to be on the wet side. So our argument is  
19 actually consistent with what is being said here because it  
20 makes a distinction between a detector and it says it  
21 includes a processing unit, which is very likely to be  
22 electronic in nature. So in the systems in the patent,  
23 there has to be a detector, and it's not going to be inside  
24 the box, because that would be a fluidics component.

25 THE COURT: Right.

1 MR. MILLER: So in Bergstrom, in that particular  
2 piece of prior art, I guess they were all one piece, and so  
3 it says that they're going to be -- there's going to be  
4 electronic -- it says, liquid and electrical parts sit side  
5 by side in the module in the baseplate.

6 So, again, what they are saying is that, hey,  
7 look, there's no non-fluidics section here. They are not  
8 saying, and the word all appears nowhere in any of this  
9 prosecution --

10 THE COURT: No, but it's saying liquid and  
11 electrical parts sit side by side as opposed to your  
12 invention. But your invention -- I mean, if you want to  
13 buy -- you know, you are saying that, well, no, we've got  
14 a pH electrode that's electric which sits by side with  
15 fluidics components. You are saying it's actually attached  
16 to a fluidics component.

17 MR. MILLER: Yes. It's inside of something  
18 that's inside of the pH module.

19 THE COURT: How do you reconcile that with the  
20 statement that says, what distinguishes and makes patentable  
21 your patent is that, "liquid and electrical parts sit side  
22 by side in Bergstrom but they don't in yours"?

23 MR. MILLER: Because it's saying in the  
24 non-fluidics section, there aren't going to be -- in the  
25 non-fluidics section, there won't be any electronics. It

1 doesn't say anything about what is going to be in the  
2 fluidics section. It's just saying, hey, look, we have a  
3 non-fluidics section. Your prior art does not teach a  
4 non-fluidics section. That's the distinction. So that  
5 can't arise to a clear and unmistakable disavowal because  
6 they are talking about two different things.

7           What they are saying is, hey, look, you need to  
8 move all of the electronics into the, into this non-fluidics  
9 section. All they were saying is like, look, what you are  
10 pointing to as a non-fluidics section, it's not a  
11 non-fluidics section because it has electronic components in  
12 it.

13           THE COURT: But it says, look at slide 59. In  
14 Bergstrom, the opposite is taught. Fluid and non-fluidic  
15 parts are together, and you are saying, no. You know,  
16 because of the definition you want me to adopt, you want a  
17 one-way street. You don't want to have reciprocity, so you  
18 want to have non-fluidic as defined as not including  
19 fluidic, but fluidic sections not defined as barring  
20 non-fluidics, and yet --

21           MR. MILLER: And -- I'm sorry. Go ahead.

22           THE COURT: And then to overcome the objection,  
23 you say in Bergstrom the fluid and the non-fluidic parts are  
24 together, which is what you want to have now in the fluidics  
25 section.

1 MR. MILLER: Well, but the entire discussion is  
2 about what the Examiner was saying was a non-fluidics  
3 section.

4 So the non-fluidics section --

5 THE COURT: Show me where it is clear from the  
6 prosecution history they are only talking about a  
7 "non-fluidic section."

8 MR. MILLER: Give me a moment, Your Honor.

9 (Pause.)

10 MR. MILLER: Are you looking at Exhibit D?

11 THE COURT: Yes, I'm there.

12 MR. MILLER: I think if you go to 1477. In the  
13 heat of the moment, this is all I can do right now.

14 THE COURT: Okay. I'm there.

15 MR. MILLER: At the top there it says, wherein  
16 this -- one, two, three, four, five lines down.

17 THE COURT: Okay.

18 MR. MILLER: It says, wherein the liquid  
19 handling panel, the objects are arranged such that each  
20 external fluidics of the unit is separated from its  
21 respective modular section by the liquid handling panel. It  
22 says it is not disclosed in the prior art.

23 So, and then they made a claim to say that the  
24 fluidics section comprised electronics and electrical  
25 components. And I would submit that that is support to us,

1 right, because electronics components are explicitly recited  
2 in the claim.

3 So that's what they are talking about, there's  
4 no electronic components in the fluidics section. They  
5 would be crazy to do so because the specification literally  
6 describes several examples where there are electronics on  
7 the fluidics side.

8 MR. BILSKER: Your Honor, I apologize for  
9 interrupting, but did he say page 1477?

10 THE COURT: Yes.

11 MR. BILSKER: Okay.

12 MS. SKLENAR: Your Honor, if I can just  
13 interrupt for a second. This is Ms. Sklenar.

14 If I could propose a compromise position in  
15 order to address some of the comments that Your Honor has  
16 made, but also try to get at the issue that I think we're  
17 concerned about.

18 THE COURT: Okay.

19 MS. SKLENAR: If we could look at Figure 4A,  
20 I can give you my proposed compromise with reference to  
21 that.

22 THE COURT: Okay.

23 MS. SKLENAR: In light of Your Honor's comments,  
24 we could agree to construction where there needs to be a  
25 fluidics section with only fluidics, and that there needs to



1 be a non-fluidics section that can't have fluidics, but what  
2 we're trying to preserve and carve out is this idea that  
3 it's possible that there could be another section somewhere  
4 on the module -- you know, not in the fluidics section, but  
5 somewhere else. For example, if we look at Figure 4A and  
6 you see 28, which was the panel number, what we're trying to  
7 prevent is someone from saying, we don't infringe this claim  
8 if we have, say, stuck in the panel member 28 some lights.  
9 So they'll say, well, there's electronics there and it's not  
10 in the non-fluidics section.

11 So if Bio-Rad's construction is adopted, which  
12 says all electronics for the module have to be in the  
13 non-fluidics section, they would basically be excluding that  
14 configuration from the claim where you got electronics  
15 elsewhere but they are not in the fluidics section.

16 THE COURT: But, see, actually, this is very  
17 interesting that you propose this. If you recall, I  
18 actually led with the questions that exactly went to this  
19 issue, because my first question was about, can you have, do  
20 you have to have electronic components in the fluidics  
21 section, because I think it's clear that the written  
22 description allows for there to be non-fluidic components  
23 external to the non-fluidics section. They just, and I  
24 think this is a key, they just can't be in the fluidics  
25 section.

1                   So basically, what you are saying makes sense to  
2 me, I think. Let's hear from Bio-Rad says.

3                   MR. BILSKER: Absolutely not, Your Honor.

4                   THE COURT: Why not?

5                   MR. BILSKER: Because again, it begs the  
6 question. What is a section? They want to say you can have  
7 a fluidics section, because if I have -- if I have this  
8 fluid line here, I will draw a circle around this fluid line  
9 and I'm going to call that a fluidics section, and then if I  
10 have more fluidics on the side and they're next to  
11 electronic parts, I'm not going to call those part of the  
12 fluidics section. Those are a different section. And that  
13 is completely inconsistent with the representation that they  
14 made about Hess.

15                   And let me just -- the reason I asked whether he  
16 was pointing to page 1477 is because 1477 is talking about  
17 Mourtada. It's not talking about Bergstrom.

18                   And if we go back to the slides on Hess --

19                   THE COURT: No, no. Don't go there yet. Let's  
20 just finish up. You see, look, if you've got --

21                   MR. BILSKER: Again, that's not what they  
22 claimed.

23                   THE COURT: Just hold on a second, please. I  
24 mean, what I understand the compromise is, essentially, if  
25 you agree with Bio-Rad, that if you have a non-fluidics

1 section, there can't be any fluidics in it, and a fluidics  
2 section would mean there's no non-fluidics in it.

3 But could there be, in addition to those two  
4 sections, a third section, and you could have a mix. And as  
5 I look at claim 1, for instance, of the '591 patent, it has  
6 an external fluidics section. It has to have one. It has  
7 to have an internal non-fluidics section. So both of those  
8 sections would have to exist and would have to have in one  
9 case, the fluidics section, no non-fluidic component. In  
10 the second case, the non-fluidic section could not have any  
11 fluidic component.

12 And then it has to have a separate section,  
13 which is something distinct and different and is not within  
14 those two sections, and Bio-Rad here is saying you can't  
15 live with that.

16 MR. BILSKER: Absolutely not. Again, it begs  
17 the question. What is the section at that point? So I have  
18 a module and I have an outside part of it and I'm going to  
19 split it up into little, little piles, and I'm going to say,  
20 hey, I've actually got 45 different sections here on this  
21 module, 45 different sections on the outside. You know, I  
22 don't -- there's a bunch of electronics, but they're all on  
23 the top half. So because they're on the top half, I'm going  
24 to call only the bottom half my fluidics section and I'm not  
25 going to call the top half my fluidics section, and that's

1 just not what they said during the prosecution. The section  
2 was defined as all parts of that type, and that's again, if  
3 we go through slide 58, 59 --

4 THE COURT: But I guess what I'm getting at it  
5 is, I think, GE, would you agree then, would you agree to  
6 Bio-Rad's construction?

7 MS. SKLENAR: No, because our issue with their  
8 construction is that it says essentially all electronics for  
9 the module, for the entire module have to be in a  
10 non-fluidics section. And, again, that would allow --

11 THE COURT: Fair enough. So what if it just  
12 said though, a section -- yes. I mean, you know, here's  
13 where I am. I will just tell you right now.

14 So I'm not able to accept GE's position that on  
15 one hand a non-fluidic section can contain fluidics. On the  
16 other hand, a fluidics section cannot contain non-fluidics.  
17 On the other hand, the patent uses the indefinite article,  
18 so it contemplates one or more sections, and the Federal  
19 Circuit has said, understandably, that the indefinite  
20 article does not mean all.

21 So that is what I find problematic about  
22 Bio-Rad's construction, is they want to say all the fluidic  
23 components.

24 MS. SKLENAR: Yes. I apologize.

25 THE COURT: That's all right. You know, but GE,

1     you know, I can't live with the way you want to interpret  
2     it.

3                 MS. SKLENAR: Yes. If we can put all of our  
4     cards on the table.

5                 THE COURT: Well, that's helpful.

6                 MS. SKLENAR: The reason we're fighting about  
7     this is because Bio-Rad wants to argue for noninfringement  
8     that they have some electrical components like lights that  
9     are in the panel member, so neither of the sections we're  
10    talking about, the fluidics or non-fluidics, but are in the  
11    panel member.

12                So, for example, what we see in Figure 4A at 28,  
13    they want their construction so they can then turn around  
14    and say, we don't infringe because we don't have all of our  
15    electrical components in one section. And what we're  
16    submitting -- and, again, we are modifying our approach. We  
17    are willing to agree that a fluidics section cannot have  
18    electronics or electrical components, but what we can't live  
19    with is this notion that somehow you could get outside of  
20    the scope of this claims by putting little lights in a  
21    different section.

22                THE COURT: But that is not before you. Right?  
23    You kind of did an all-or-nothing in your proposal. I mean,  
24    it seems to me you could have been more judicious in the  
25    proposal and then left this issue for trial and figure it

1 out.

2 So why don't we just step back and let's go  
3 with, I'm looking at page 94 of your brief where we've got  
4 the competing construction proposals for fluid handling  
5 section. Right? And you've got a section of the  
6 interchangeable fluid handling unit that includes fluidics  
7 components.

8 So why don't you just change that to be  
9 consistent with your construction of a non-fluidic section  
10 and say that this would be a section of the interchangeable  
11 fluid of the interchangeable fluid handling unit that does  
12 not include electrical components.

13 MS. SKLENAR: And we're willing to do that, Your  
14 Honor. It's the all issue we can't live with.

15 THE COURT: Okay. But, you know, then that's  
16 fair and I think that's a legitimate complaint. So here's  
17 where I am. That's how I'm going to interpret these terms.

18 I'm going to interpret non-fluidics section to  
19 mean, "a section of the interchangeable fluid handling unit  
20 that includes electrical components and does not include  
21 fluidics components."

22 I'm going to construe a fluid handling section  
23 to mean, "a section of the interchangeable fluid handling  
24 unit that includes fluidics components and does not include  
25 non-fluidics components." And that seems to me to be the

1 most reasonable construction. That is consistent with what  
2 I think were clear and unequivocal statements to distinguish  
3 this patent from Bergstrom and Hess, because the basis of  
4 the distinctions to the Patent Examiner were that this  
5 patent had two sections that, at least two sections, one is  
6 non-fluidic, one is fluidic, that are separated completely  
7 and that do not contain components of the other section.

8 That does not, however, preclude the possibility  
9 that there are other sections that are in the invention, and  
10 that's important because that is consistent with the use of  
11 the indefinite article, which is inconsistent with Bio-Rad's  
12 insistence that "all," either fluidic or non-fluidic  
13 components, are in the respective handling unit.

14 So that actually seems to me is the right result  
15 in this case and I'm going to construe then these last group  
16 of terms in that manner.

17 All right. Is there anything else for me to  
18 construe?

19 MS. SKLENAR: Nothing from plaintiff, Your  
20 Honor.

21 MR. BILSKER: Mr. Bilsker. None.

22 THE COURT: Okay. I'm going to ask the  
23 plaintiff to submit within a week from today a written order  
24 of the claim chart and the basis of my rulings are set forth  
25 in today's telephone conference.

1 I read the briefs carefully. I've articulated  
2 the general basis of my rulings. I'm cognizant that there's  
3 de novo review in the Federal Circuit, so that really no  
4 matter what I say has really no consequence, but I  
5 appreciate the briefing and the arguments of the parties  
6 today. And if you will just submit that order that is  
7 consistent with my rulings today within a week, I will sign  
8 it forthwith.

9 Anything else from the plaintiffs?

10 MS. SKLENAR: Nothing, Your Honor. Thank you so  
11 much for your time.

12 THE COURT: Anything from the defense?

13 MR. BILSKER: I was just curious about the  
14 transcript, but I guess we can handle it.

15 THE COURT: What do you mean?

16 MR. BILSKER: Whether we would get the  
17 transcript just to make sure that the order is consistent  
18 with the transcript. I was having a little trouble writing  
19 as quickly as you were speaking.

20 THE COURT: Well, let's actually, before we  
21 leave, where is there any ambiguity in what I've ruled on in  
22 your mind?

23 MR. BILSKER: I don't think there's ambiguity.  
24 I just didn't have the exact words that you said. I didn't  
25 get a chance to write them down exactly. Maybe my associate



1 did. That's all I was saying.

2 THE COURT: No, that's fair. And, really, I  
3 think the big point is, it is kind of the thing that  
4 disturbed me from the beginning with the plaintiffs'  
5 argument, is on those last two, the fluidics and the  
6 non-fluidics, I just interpreted it as far as I'm concerned  
7 in a manner that's consistent, and I think that Bio-Rad even  
8 agreed insofar as it being consistent. That's the big  
9 distinction there.

10 So, okay. If because of the current situation  
11 you need more time to get the order in, to get the  
12 transcript ready, that's fine, but at least as of now we'll  
13 set it for a week from today, and the obligation will be on  
14 plaintiffs to submit the proposed claim construction order.  
15 Okay?

16 Everybody have a great day. Stay safe. Thanks  
17 very much. Bye-bye.

18 (Counsel respond, "Thank you, Your Honor.")

19 (Telephone conference concluded at 1:12 p.m.)

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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB and	)	
GLOBAL LIFE SCIENCES	)	
SOLUTIONS USA LLC,	)	
	)	
	)	C.A. No. 18-1899-CFC
Plaintiffs,	)	Consolidated
	)	
v.	)	<b>HIGHLY CONFIDENTIAL-</b>
	)	<b>FILED UNDER SEAL</b>
BIO-RAD LABORATORIES, INC.,	)	
	)	
Defendant.	)	

**Declaration of Nenad Vukicevic**

1. Counsel for Cytiva Sweden AB and Global Life Sciences Solutions USA LLC. (which I will refer to herein as “Cytiva”) have engaged me in this case. I have been compensated at a rate of \$325 per hour for my consulting work. My compensation is not contingent upon the outcome of this case. I am submitting this declaration at the request of Cytiva.

2. I obtained a BS degree in Electrical Engineering from the University of Belgrade, Serbia, and have 39 years of experience in embedded systems, computer languages, high-performance computing, and application development on many

HIGHLY CONFIDENTIAL - SOURCE CODE

systems. I have been employed by Intrepid Technology since 1989, where I am one of the founding partners. I have experience and familiarity with many programming languages and have extensive experience reviewing source code for litigation matters.

3. I was asked to review certain source code produced by Bio-Rad Laboratories, Inc. (“Bio-Rad”) executed by Bio-Rad’s NGC liquid chromatography system.

4. The source code was produced in the form of multiple folders, labeled as ChromLabvX.YSource. These folders appear to be different versions of the software for the NGC system, titled Versions 3.1, 3.2, 3.3, 4.0, 5.0.2, and 6.0. A review of each folder revealed a similar folder structure for each of them. For the code review, I focused mainly on the latest, version 6.0, and verified that the code is not different in any significant way for the other versions.

5. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

6. [REDACTED]

[REDACTED]

HIGHLY CONFIDENTIAL - SOURCE CODE

[REDACTED]

7.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

8.

[REDACTED]

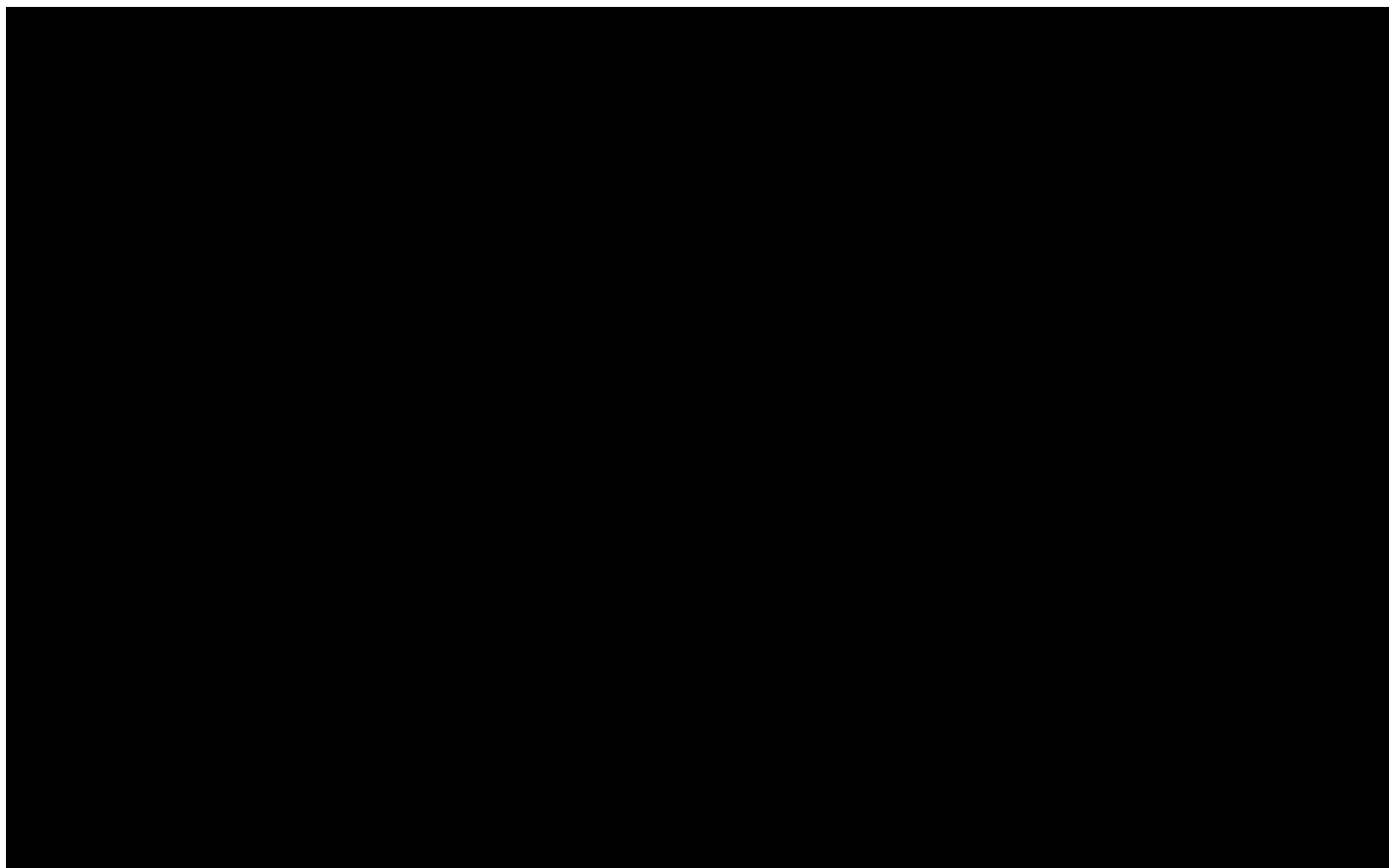
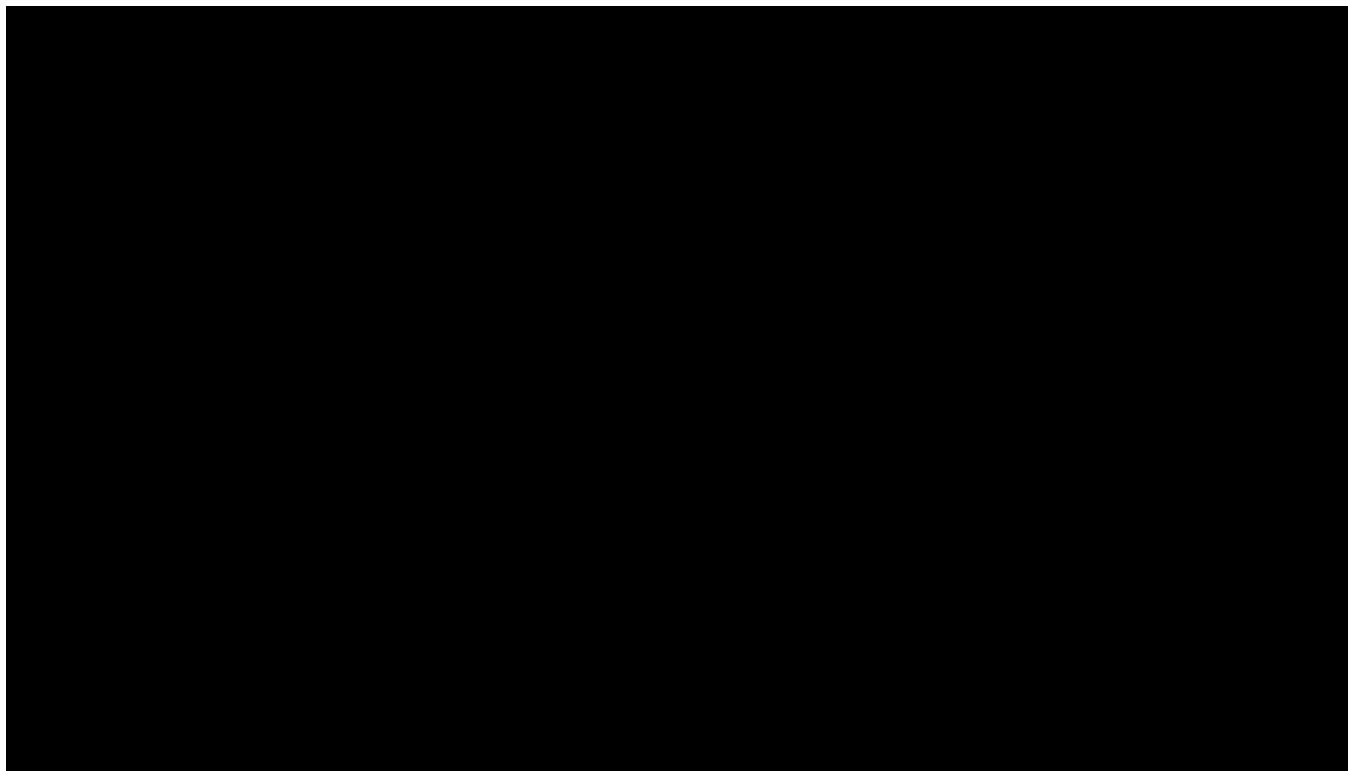
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

HIGHLY CONFIDENTIAL - SOURCE CODE



HIGHLY CONFIDENTIAL - SOURCE CODE

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

12. I declare under penalty of perjury under the laws of the United States of America that the foregoing is a true and correct statement of my opinions and the supporting facts and that this declaration was executed on December 15, 2020 at Half Moon Bay, California.

Dated: December 15, 2020



---

Nenad Vukicevic

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

CYTIVA SWEDEN AB and	)	
GLOBAL LIFE SCIENCES	)	
SOLUTIONS USA LLC,	)	
	)	
Plaintiffs,	)	C.A. No. 18-1899-CFC
	)	Consolidated
	)	
v.	)	
	)	
BIO-RAD LABORATORIES, INC.,	)	
	)	
Defendant.	)	

**DECLARATION OF JEFFREY A. MILLER IN SUPPORT OF  
PLAINTIFFS' OPENING BRIEF IN SUPPORT OF ITS MOTION FOR  
SUMMARY JUDGMENT OF INFRINGEMENT OF  
CLAIM 1 OF U.S. PATENT NO. 9,671,420,  
CLAIM 1 OF U.S. PATENT NO. 9,709,589,  
CLAIM 14 OF U.S. PATENT NO. 9,709,591, AND  
CLAIM 16 OF U.S. PATENT NO. RE47,124**

I, Jeffrey A. Miller, declare and state as follows:

1. I am a partner with Arnold & Porter Kaye Scholer LLP, counsel of record for plaintiffs Cytiva Sweden AB and Global Life Sciences Solutions USA LLC (together, “Cytiva”) in this action. I provide this declaration in support of Cytiva’s Motion for Summary Judgment of Infringement Claim 1 of U.S. Patent No. 9,671,420, Claim 1 of U.S. Patent No. 9,709,589, Claim 14 of U.S. Patent No. 9,709,591, and Claim 16 of U.S. Patent No. Re47,124.

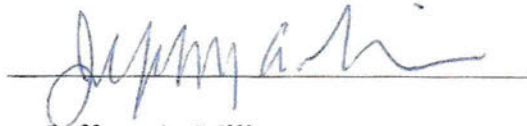
2. I have personal knowledge of the facts stated herein and, if called as a witness, could and would testify competently thereto.

3. Attached hereto as **Exhibit 8** is a true and correct copy of excerpts of the Deposition Transcript of Dr. Bruce Gale.

4. Attached hereto as **Exhibit 9** is a true and correct copy of excerpts of the publicly available document, titled “NGC Chromatography Systems and ChromLab Software User Guide Version 6.0.”

5. Attached hereto as **Exhibit 15** is a true and correct copy of the Expert Rebuttal Report of Dr. Bruce Gale, served on October 21, 2020.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on December 15, 2020 in Palo Alto, California.



Jeffrey A. Miller



# **EXHIBIT 8**

**FILED UNDER SEAL**

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Bruce Gale, Ph.D.

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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

-----  
Cytiva Sweden AB and Global Life  
Sciences Solutions USA, LLC,

Plaintiff,

Case No.

18-1899-CFC

-against-

Bio-Rad Laboratories, Inc.,

Defendant.  
-----

HIGHLY CONFIDENTIAL  
VIDEO-RECORDED DEPOSITION OF  
DR. BRUCE GALE  
Zoom Videoconference  
11/25/2020  
8:28 a.m. (MT)

REPORTED BY: AMANDA GORRONO, CLR

CLR NO. 052005-01

\_\_\_\_\_  
DIGITAL EVIDENCE GROUP  
1730 M Street, NW, Suite 812  
Washington, D.C. 20036  
(202) 232-0646

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11/25/2020

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8:28 a.m. (MT)

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4

VIDEO-RECORDED DEPOSITION OF DR. BRUCE GALE,

5

held virtually via Zoom Videoconferencing, before

6

Amanda Gorrone, Certified Live Note Reporter, and

7

Notary Public of the State of New York.

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1 A P P E A R A N C E S

2 (Via Zoom Videoconferencing

3

4 ON BEHALF OF PLAINTIFF: CYTIVA SWEDEN AB AND GLOBAL  
LIFE SCIENCES SOLUTIONS USA, LLC:

5 Jennifer Sklenar, Esquire

Arnold & Porter Kaye Scholer LLP

6 601 Massachusetts Ave, NW

Washington, D.C. 20001-3743

7 PHONE: 202.942.5786

8 E-MAIL: Jennifer.sklenar@arnoldporter.com

9

10 ON BEHALF OF DEFENDANT: BIO-RAD LABORATORIES, INC.:

Sean Damon, Esquire

11 Quinn Emanuel Urquhart & Sullivan, LLP

1300 I Street NW

12 #900

Washington, D.C. 20005

13 PHONE: 202-538-8260

E-MAIL: Seandamon@quinnemanuel.com

14

15

16 ALSO PRESENT:

17 Brian Cannon, Esquire, on behalf of Bio-Rad, Quinn

18 Emanuel Urquhart & Sullivan, LLP

19 Andy Mortensen, legal videographer, Digital Evidence

20

21

22

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# I N D E X

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WITNESS

EXAMINATION BY

PAGE

4

DR. BRUCE GALE

MS. SKLENAR

7

5

6

## E X H I B I T S

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8

EXHIBIT

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Exhibit 326 Dr. Gale's Opening Report.....

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Exhibit 332 Declaration of Dr. Bruce Gale...

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Exhibit 333 Declaration of Dr. Bruce Gale

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Exhibit 334 Declaration of Dr. Bruce Gale

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in support of Bio-Rad

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3 EXHIBIT DESCRIPTION PAGE

4 Exhibit 335 List of Programs on the 2040

5 Instrument..... 194

6 Exhibit 336 2040 System Test Report..... 244

7 Exhibit 337 NGC chromatography systems and

8 ChromLab software instrument

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10 Exhibit 338 Bio-Rad Hardware Specification.. 367

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1 THE VIDEOGRAPHER: Stand by please.

2 This begins the media of the  
3 videotaped deposition of Dr. Bruce Gale, taken by  
4 Counsel for the plaintiffs in the matter of Cytiva  
5 Sweden AB and Global Life Sciences Solutions USA  
6 LLC, versus Bio-Rad Laboratories, Inc., in the United  
7 States District Court for the District of Delaware,  
8 Case No. 18-1899-CFC.

9 This deposition is being conducted by  
10 Zoom and recorded in Irving, Texas, on November 25,  
11 2020. The time on the video screen is 8:28 a.m.  
12 Mountain Time.

13 My name is Andy Mortensen. I'm the  
14 legal videographer from Digital Evidence Group. The  
15 court reporter is Amanda Gorrone, in association with  
16 Digital Evidence Group.

17 All parties for this deposition are  
18 appearing remotely and have agreed to the witness  
19 being sworn in remotely. Due to the nature of remote  
20 reporting, please pause briefly before speaking, to  
21 ensure all parties are heard completely.

22 Will counsel please introduce

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1 themselves for the record?

2 MS. SKLENAR: Yes. Good morning. My  
3 name is Jennifer Sklenar. I'm with Arnold & Porter  
4 representing plaintiffs.

5 MR. DAMON: Good morning. Sean Damon  
6 and Brian Cannon on behalf of Bio-Rad, from Quinn  
7 Emanuel.

8 THE VIDEOGRAPHER: Thank you. Will  
9 the court reporter please swear in the witness?  
10 D R. B R U C E G A L E, called as a witness,  
11 having been first duly sworn by a Notary Public of  
12 the State of New York, was examined and testified as  
13 follows:

14 EXAMINATION BY

15 MS. SKLENAR:

16 Q. Good morning, Dr. Gale.

17 A. Good morning.

18 Q. Could you please state your full name  
19 for the record?

20 A. Bruce Kent Gale.

21 Q. And you are an expert witness in this  
22 case for Bio-Rad, correct?



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1 agreements produced by Bio-Rad and Cytiva other than  
2 the two you've summarized?

3 A. Actually, I think there were like six  
4 or eight or some number of license agreements. I  
5 don't remember specifically. They were -- there were  
6 more than two.

7 Q. You don't summarize any agreements  
8 other than the [REDACTED]  
9 [REDACTED], correct?

10 A. That's correct.

11 Q. [REDACTED]

12 [REDACTED]

13 [REDACTED] [REDACTED]

14 [REDACTED] [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED] [REDACTED]

18 [REDACTED]

19 [REDACTED] [REDACTED] [REDACTED]

20 [REDACTED]

21 Q. And liquid chromatography is to  
22 separate biological materials, right?

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1           A.           Yeah. I mean, the mechanisms are  
2     different but they are both used to do analytical  
3     measurements.

4           Q.           But they are different technologies.  
5     Can we agree on that?

6           A.           Sure.

7           Q.           Okay. Let's keep moving. And I want  
8     to turn now to a new topic.

9                       And that's the meaning of the term  
10    "automated liquid chromatography" --

11                   MS. SKLENAR: Strike that.

12          Q.           -- "automated liquid chromatography  
13    system." You understand that Dr. Wereley has  
14    provided what he believes is an automated liquid  
15    chromatography system, correct?

16          A.           I -- I mean, I recall reading  
17    something to that effect.

18          Q.           And if we turn to his rebuttal  
19    report, let's see, Paragraph 320. Are you there?

20          A.           I am.

21          Q.           Okay. It's Page 396, Paragraph 320,  
22    he says, "In my opinion, a POSITA would understand

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1 that an automated liquid chromatography system  
2 requires many ... components," and then he goes onto  
3 list them. Do you see that?

4 A. Yes.

5 Q. Okay. And I just want to ask you,  
6 first of all, is it your understanding that the NGC  
7 system is an automated liquid chromatography system?

8 MR. DAMON: Objection.

9 A. I believe it's been characterized as  
10 that. I mean, some of this goes to how you define  
11 some of these terms so -- I guess it -- in general, I  
12 know that it's, you know, intended to do liquid  
13 chromatography and that it can do many of these  
14 things in an automated fashion, but I also know that  
15 those terms mean something very specific in this  
16 patent and it may or may not meet those specific  
17 terms.

18 Q. You haven't taken a position that the  
19 NGC system is not an automated liquid chromatography  
20 system as you understand the term, correct?

21 MR. DAMON: Objection; form.

22 A. Yeah. I don't -- I don't think I

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1 wrote anything to that effect that it's not an  
2 automated liquid chromatography system, but as noted,  
3 you know, there's -- some of these claims or some of  
4 these terms are used sometimes that may or may not  
5 fit, I guess.

6 Q. But you haven't pointed out any  
7 instances where you think the NGC system could be  
8 considered something different than an automated  
9 liquid chromatography system, right?

10 MR. DAMON: Objection to form.

11 A. Yeah. I don't recall right off that  
12 I did anything to that effect.

13 Q. So you agree that the NGC system has  
14 an injection valve?

15 MR. DAMON: Objection; form.

16 A. I mean, it can, yes.

17 Q. And you agree that the NGC system has  
18 a sample pump?

19 A. I know that the NGC system has some  
20 pumps, yes.

21 Q. And the pumps are used to pump  
22 sample, correct, in the NGC system?

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1           A.           That they -- I believe there is a  
2     sample pump.

3           Q.           And the NGC systems have control  
4     software, right?

5                       MR. DAMON:   Objection.

6           A.           Yeah.   As far as I know, there's  
7     software that runs the instrument.

8           Q.           And the NGC system has in-line  
9     detectors, right?

10                      MR. DAMON:   Objection; form.

11           A.           I believe it has some detectors that  
12     are included.

13           Q.           And it has in-line detectors,  
14     correct, the NGC system?

15                      MR. DAMON:   Objection; form.

16           A.           Yeah.   Yeah, that's my understanding.

17           Q.           And those in-line detectors in the  
18     NGC system can measure characteristics of the liquid  
19     existing the chromatography column, right?

20           A.           Yeah.   I guess I don't have any  
21     reason to object to that.

22           Q.           So let's go to Tab O?

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1 THE TECH: (Complying.)

2 MS. SKLENAR: And mark it as next in  
3 order.

4 (Whereupon, Exhibit 337, NGC  
5 chromatography systems and ChromLab software  
6 instrument guide, was marked for identification.)

7 MS. SKLENAR: What's the number? I'm  
8 sorry.

9 THE TECH: The next number is 336 --  
10 no, I'm sorry. 337.

11 MS. SKLENAR: 337.

12 BY MS. SKLENAR:

13 Q. So Exhibit 337 is the NGC  
14 chromatography systems and ChromLab software  
15 instrument guide. Do you see that?

16 A. I do.

17 Q. Is this a document you've reviewed?

18 A. I have looked at it, yes.

19 Q. Let's turn to Page 65. Let's look at  
20 the very bottom portion under UV detectors and  
21 conductivity monitor. It says, "UV detectors measure  
22 the UV absorbance of biomolecules as they elute

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1 through the column." Do you see that?

2 A. I do.

3 Q. UV absorbance is a characteristic of  
4 the sample that's eluted from the column, right?

5 A. That's true.

6 Q. Okay. So what this is saying is that  
7 the UV detector can measure the absorbance after the  
8 liquid leaves the column, right?

9 A. That's correct.

10 Q. And every model of Bio-Rad's NGC  
11 liquid chromatography product includes a UV monitor,  
12 right?

13 MR. DAMON: Objection; form.

14 A. I don't specifically recall, but I  
15 think that's true.

16 Q. And the UV module in Bio-Rad's NGC  
17 systems measures UV absorbance and a conductivity of  
18 the fluids that have passed through the column,  
19 right?

20 A. Sorry. Can you say that one more  
21 time?

22 Q. The UV module in the Bio-Rad NGC

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Bruce Gale, Ph.D.

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1 systems measures UV absorbance and conductivity of  
2 the fluids that have passed through the column?

3 MR. DAMON: Objection.

4 A. I don't recall if the UV monitor  
5 measures conductivity or not. I don't know.

6 Q. But at least in terms of -- so you  
7 don't know that one way or another?

8 A. You know, I don't recall if it has a  
9 conductivity measurement in that system, in the UV  
10 monitor system.

11 Q. At the very least it measures the UV  
12 absorbance of the fluids that pass through the  
13 column, correct?

14 A. That's correct.

15 Q. Okay. Are you aware of column valves  
16 that issued in the prior art with integrated pressure  
17 sensors prior to the 2009, 2010 time period?

18 MR. DAMON: Objection; form.

19 A. I don't recall when those became  
20 common.

21 Q. So you're -- you don't know one way  
22 or another; is that right?



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1 MR. DAMON: Objection.

2 A. Yeah. I don't -- I don't  
3 specifically remember, yeah, when that occurred.

4 Q. Are there -- would you expect a  
5 column valve with an integrated pressure sensor to  
6 have any electronics or electrical components on the  
7 front-facing portion?

8 MR. DAMON: Objection; form.

9 A. I mean, it could. It's certainly not  
10 required.

11 Q. Okay. But you're aware of column  
12 values with integrated pressure sensors that have  
13 electrical components or electronics on the outside  
14 of the housing; is that right?

15 MR. DAMON: Objection; form.

16 A. Yeah. I mean, like I said, it's --  
17 it's there are electronic pressure sensors, there's  
18 mechanical pressure sensors. Anyways, there's --  
19 there are ones that have electronic pressure sensors.

20 Q. For -- sorry, you just said  
21 electronic pressure sensors and mechanical pressure  
22 sensors, right?

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1 CERTIFICATE OF SHORTHAND REPORTER-NOTARY PUBLIC

2 I, Amanda Gorrono, the officer before  
whom the foregoing depositions were taken, do hereby  
3 certify that the foregoing transcript is a true and  
correct record of the testimony given; that said  
4 testimony was taken by me stenographically and  
thereafter reduced to typewriting under my direction;  
5 and that I am neither counsel for, related to, nor  
employed by any of the parties to this case and have  
6 no interest, financial or otherwise, in its outcome.

7 IN WITNESS WHEREOF, I have hereunto  
set my hand this 25th day of November, 2020.

8

9

10

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13

14

AMANDA GORRONO, CLR

15

CLR NO: 052005 - 01

16

17

18 Notary Public in and for the State of New York

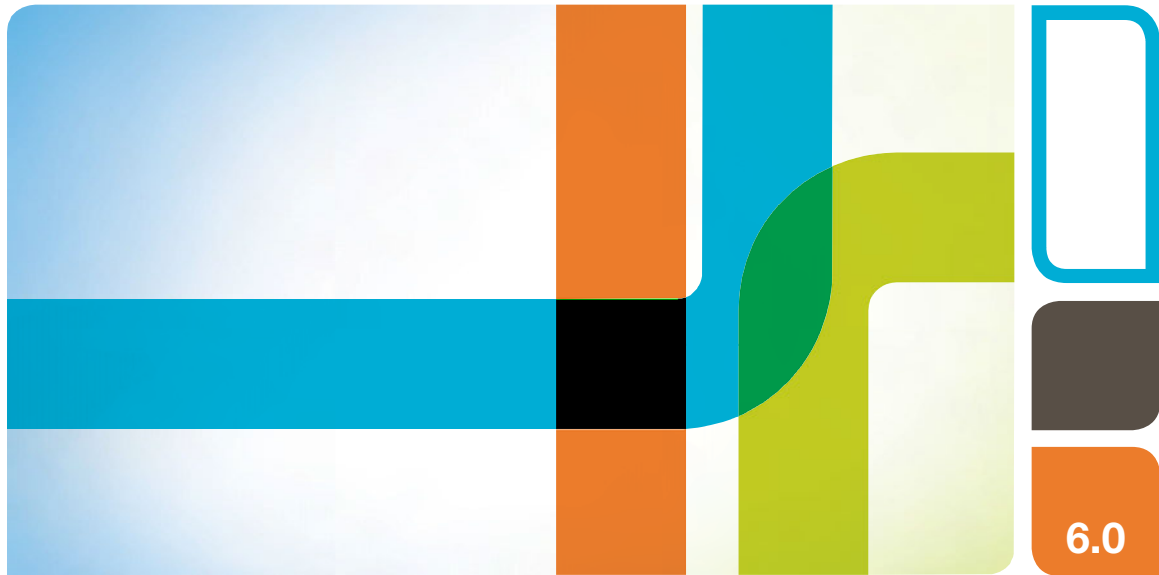
19 County of Suffolk

20 My Commission No. 01G06041701

21 Expires: 01/07/2023

22

# EXHIBIT 9



# NGC Chromatography Systems and ChromLab Software

**User Guide**  
Version 6.0



Chapman Exhibit  
7/24/2020  
**213**

# **NGC Chromatography Systems and ChromLab Software**

## **User Guide**

**Version 6.0**



## **Bio-Rad Technical Support Department**

The Bio-Rad Technical Support department in the U.S. is open Monday through Friday, 5:00 AM to 5:00 PM, Pacific time.

**Phone:** 1-800-424-6723, option 2

**Email:** [Support@bio-rad.com](mailto:Support@bio-rad.com) (U.S./Canada only)

For technical assistance outside the U.S. and Canada, contact your local technical support office or click the Contact us link at [www.biorad.com](http://www.biorad.com).

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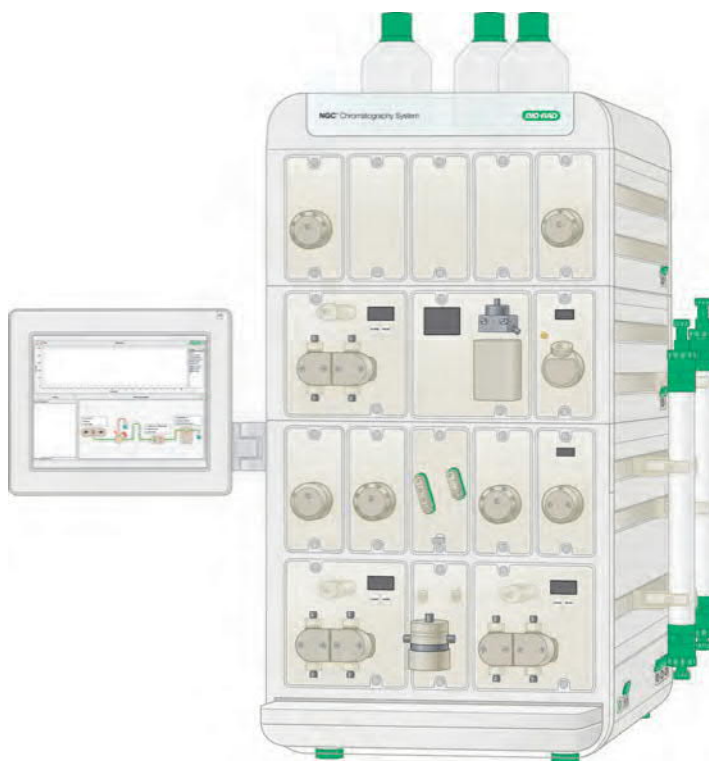
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# 1 Introduction

NGC chromatography systems provide a general purpose purification platform for purifying all forms of biomolecules using a combination of chromatography techniques. The systems are also useful for developing and optimizing purification protocols. The systems can provide highly purified proteins, peptides, nucleic acids, monoclonal antibodies, and other small molecules.



1 | Introduction

ChromLab software enables you to set up and control an NGC instrument, run protein separations and other operations manually, program methods to automate purification runs, evaluate the results, and generate and print experiment reports. This user guide explains how to perform all these tasks.

## Main NGC Features

NGC chromatography systems enable you to do the following:

- Easily create purification and maintenance protocols from predefined method templates and protocol phases
- Automate multicolumn purification processes using preprogrammed templates and multiple column switching valves
- Automate multiple sample injections using either the sample inlet valve and the sample pump or the C-96 autosampler
- Expand sample monitoring using the signal import module (SIM) to export digital signals to and import digital signals from external detectors
- Collect large-volume fractions using multiple outlet valves while also collecting small-volume fractions using the BioFrac fraction collector
- Automatically prepare buffers using preprogrammed buffer blending protocols
- Analyze purification results through 1-click peak integration, determine protein concentration and calculate column performance
- Automate purification protocol optimization using the scouting wizard
- Easily locate fractions containing peaks of interest and view the protein concentration within each fraction
- Extend the preconfigured systems with additional valves for buffers, samples, and columns



#### Main NGC Features

- Organize the location of the modules to optimize separation performance based on method scale and complexity, and to minimize the system swept volume
- Minimize errors when connecting tubing using the Point-to-Plumb feature in ChromLab software

## NGC Chromatography Systems

All NGC chromatography systems include ChromLab software and the NGC touch screen.



NGC chromatography systems are available in several combinations. Each system is equipped with either two 10 ml system pumps (the 10 series) or two 100 ml system pumps (the 100 series).

The NGC Quest chromatography system includes the following:

- Two system pumps
- Mixer
- Sample injection valve
- Conductivity monitor with either a single-wavelength UV detector or a multi-wavelength UV/Vis detector (available on the Plus systems)

## NGC Chromatography Systems

The NGC Scout chromatography system includes the following:

- All modules on the Quest system
- pH detector valve
- Buffer blending valve

The NGC Discover chromatography system includes the following:

- All modules on the Scout system
- Column switching valve
- Two buffer inlet valves
- Sample pump

The NGC Discover Pro chromatography system includes the following:

- All modules on the Discover system
- Fourth expansion tier
- Sample inlet valve
- Outlet valve

## Finding Out More

After you install NGC documentation from the NGC Chromatography Systems and ChromLab Software USB drive, you can access installed NGC guides and tutorials on the Help menu in any ChromLab view.

More information about the NGC chromatography systems and ChromLab software is available from the following sources.

- The NGC Chromatography Systems and ChromLab Software Installation Guide is available on your NGC Chromatography Systems Software USB drive as a .pdf file. This guide explains how to set up your environment, set up and install the NGC instrument in the lab, install ChromLab software, and connect ChromLab to the NGC system.
- The NGC Chromatography Systems and ChromLab Software Instrument Guide is available on your NGC Chromatography Systems Software USB drive as a .pdf file. This illustrated guide details the modules that make up the NGC instrument and includes troubleshooting and maintenance information.
- For ChromLab Help, click the question mark in the upper right corner in dialog boxes to access relevant information. Screen-level help is also available on the Help menu.
- NGC video tutorials are available on the NGC Chromatography Systems Software USB drive as .mp4 files.

**Tip:** You can click the Bio-Rad logo in the upper right corner of any ChromLab window to launch the Bio-Rad website.



## 2 The Workspace

ChromLab software provides an intuitive interface for developing chromatography methods, operating an NGC instrument, and analyzing data from chromatography runs.

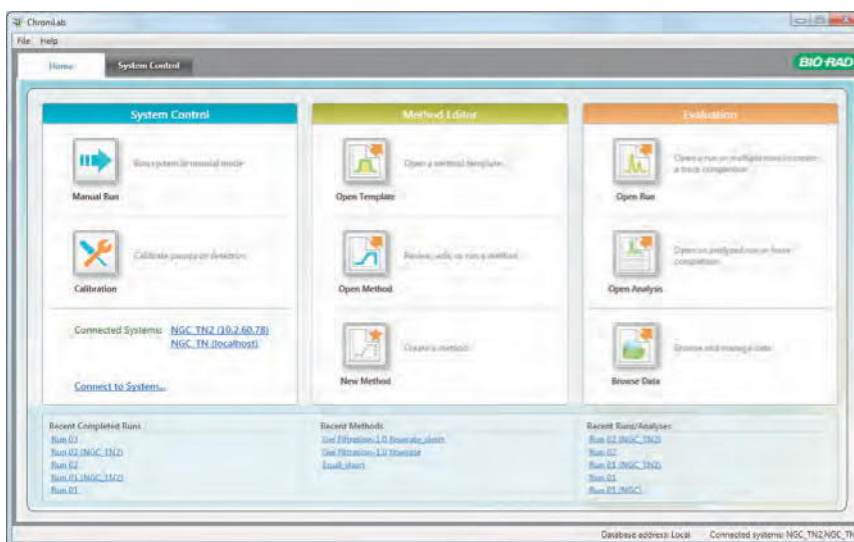
ChromLab software presents four primary workspaces.

- The Home window
- The System Control window
- The Method Editor window
- The Evaluation window

Each workspace is shown and described in this chapter. The NGC instrument touch screen is also described.

## The Home Window

ChromLab software opens with the Home window, which displays three panes and the System Control tab.

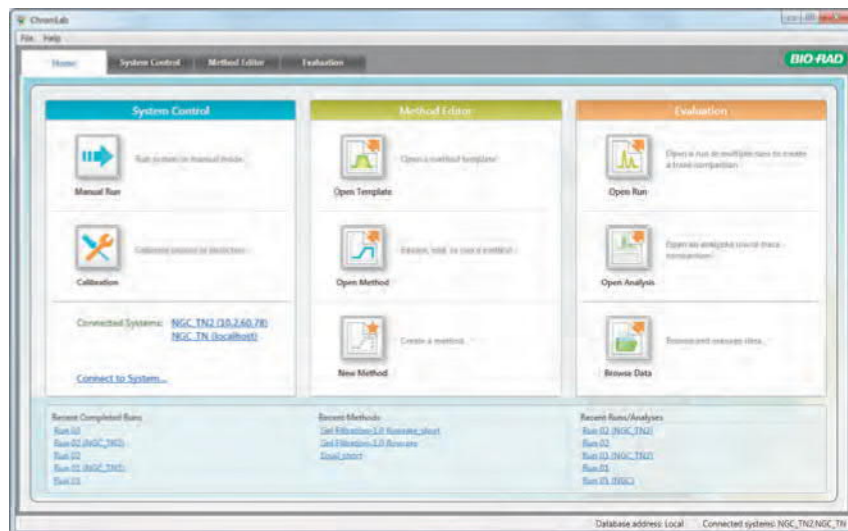


The three panes provide quick access to the system control, method editor, and evaluation workspaces, as well as to the Browse Data dialog box in which you can browse and manage your data. Links to recently viewed or completed runs, methods, and analyses appear at the bottom of each workspace pane. The name of connected NGC systems and the location of the ChromLab database appear in the status bar at the bottom of the window.

**Tip:** Clicking the Bio-Rad logo in the upper right corner of any ChromLab window launches the Bio-Rad website. Check the website often for updates to ChromLab documentation.

## The Home Window

Method Editor and Evaluation tabs become visible in the Home window when you select tasks in the Method Editor and Evaluation panes.



## File Menu Commands

**Connect to System** — starting ChromLab connects you to the most recently connected NGC instrument. ChromLab can connect to multiple NGC instruments and run methods on all connected instruments at the same time.

This command opens a dialog box that enables you to choose another NGC chromatography system to connect to. ChromLab detects the NGC systems available on the same subnetwork or a system directly connected to the computer. ChromLab displays the system name, network name, and IP address of the detected systems. To connect to a system, you can:

- Select a name in the list of detected systems and click Connect.

**Note:** If your system does not appear in the list, click Detect. ChromLab searches the network for available NGC systems and refreshes the list.

- Select the appropriate radio button, enter the system's name or IP address, and click Connect.

**Tip:** To obtain the system's name and IP address select System Information on the instrument touch screen dropdown menu.

**Disconnect System** — displays links from which you can disconnect ChromLab software from a specific NGC system or all connected NGC systems.

**Manual Run** — opens the System Control window in manual mode so you can perform a manual run or set up your system manually.

**Calibrate** — opens the Calibration dialog box, which displays instructions and options for selecting a module and calibrating it. See [Calibrations on page 74](#) for details.

**Open Template** — opens the Template dialog box in which you can select a method template from template folders organized by technique.

**Open Method** — opens a dialog box in which you can select a method to view or run. You can also select Show Runs and Analyses to display files associated with the selected method.



## The Home Window

**New Method** — opens the Method Editor window in which you can create a method using standard method phases and steps.

**Browse Data** — opens the Browse Data dialog box in which you can browse and manage your ChromLab projects, methods, runs, and analyses. See [Chapter 8, Managing ChromLab Data on page 341](#) for more information.

**Import** — displays links from which you can import the following:

- **NGC File** — opens a dialog box in which you can import a method, a method with runs, a run, or an analysis with its associated runs and method exported from ChromLab software running on another NGC system. See [Importing NGC Data Files on page 351](#) for more information.
- **Unicorn Data** — opens a dialog box in which you can import a Unicorn data file into the NGC database. See [Importing Unicorn Data Files on page 359](#) for more information.
- **DuoFlow Data** — opens a dialog box in which you can import a BioLogic DuoFlow data file into the NGC database. See [Importing BioLogic DuoFlow Data Files on page 361](#) for more information.

**Export** — displays links from which you can export the following:

- **Methods/Method Runs** — opens a dialog box in which you can export both single or multiple methods and single or multiple methods with associated runs.
- **Runs** — opens a dialog box in which you can export single or multiple runs.
- **Analyses** — opens a dialog box in which you can export single or multiple analyses with their associated runs and methods.

See [Exporting NGC Data Files on page 353](#) for more information.

**Open Run**— opens a dialog box in which you can select a run to view or analyze. You can also select Show Methods and Analyses to display files associated with the selected run.

**Open Analysis** — opens a dialog box in which you can select an analysis to view. You can also select Show Runs and Methods to display files associated with the selected analysis.

**Preferences** — opens dialog boxes in which you can do the following:

- Select pressure units for all system and software pressure values. This is a global setting. See [Units Tab on page 106](#) for more information.
- Set up an SMTP server to receive email messages about system notifications from the ChromLab computer. See [Email Server Setup Tab on page 107](#) for more information.
- Set default values for parameters used in new methods. The settings appear in the Method Settings window. See [Method Editor Tab on page 109](#) for more information.
- Create and configure a rack library for your fraction collectors. This is a global setting. See [Rack Library Tab on page 111](#) for more information.
- Set display preferences for the Evaluation window. See [Evaluation Tab on page 113](#) for more information.

**Exit** — closes ChromLab.

## Help Menu Commands

**Help** — displays screen-level help topics and links to installed manuals.

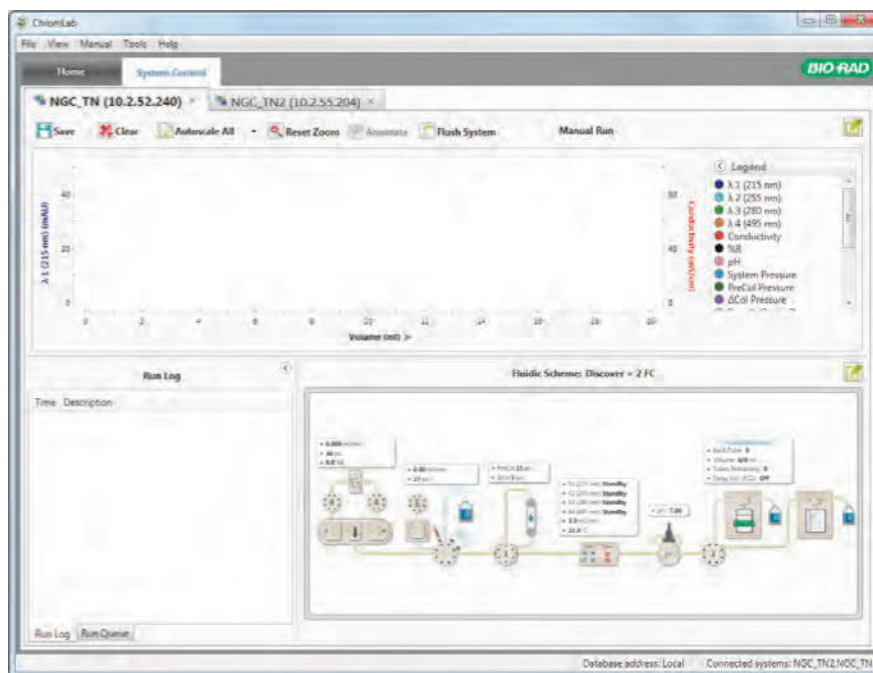
**Export Diagnostic Logs** — opens the Export Diagnostic Logs dialog box in which you can export all critical information that Bio-Rad Technical Support requires to diagnose issues. The log files and data are zipped and saved to a location that you choose. See [Exporting Diagnostic Logs on page 363](#) for more information.

**About** — displays ChromLab copyright and version information.

The System Control Window

## The System Control Window

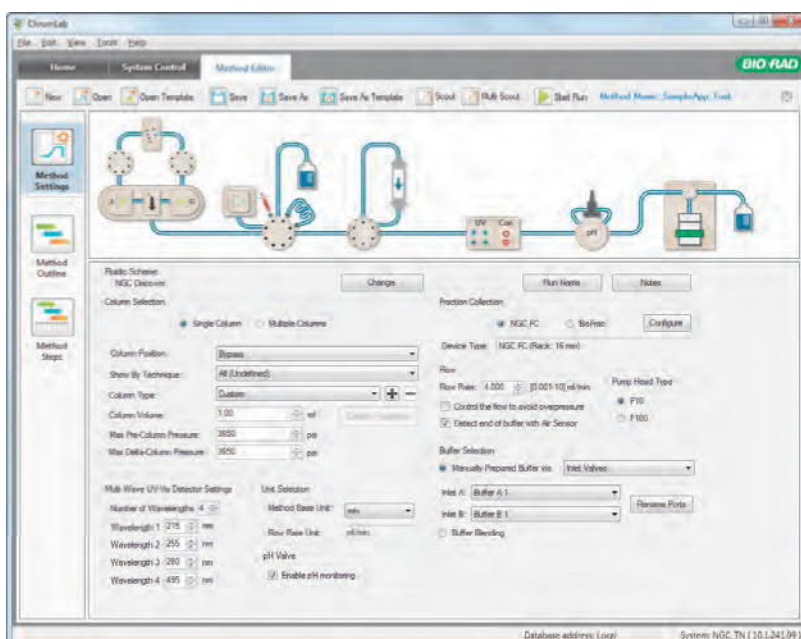
The System Control window enables you to run the NGC instruments manually, monitor method runs while they are running, select fluidic schemes, calibrate pumps and detectors, and verify the accuracy of instrument plumbing. This window displays each connected system on a separate tab. The system's tab displays a chromatogram during a run. A fluidic scheme graphically depicts the flow path of all the modules on the system. A status panel appears above each module displaying its real-time status. In manual mode, clicking a module displays its controls and detailed settings. The Run Log documents each action that occurs during a run. The Run Queue lists all runs ready to be started.



System Control functionality is detailed in [Chapter 3, System Control](#).

## The Method Editor Window

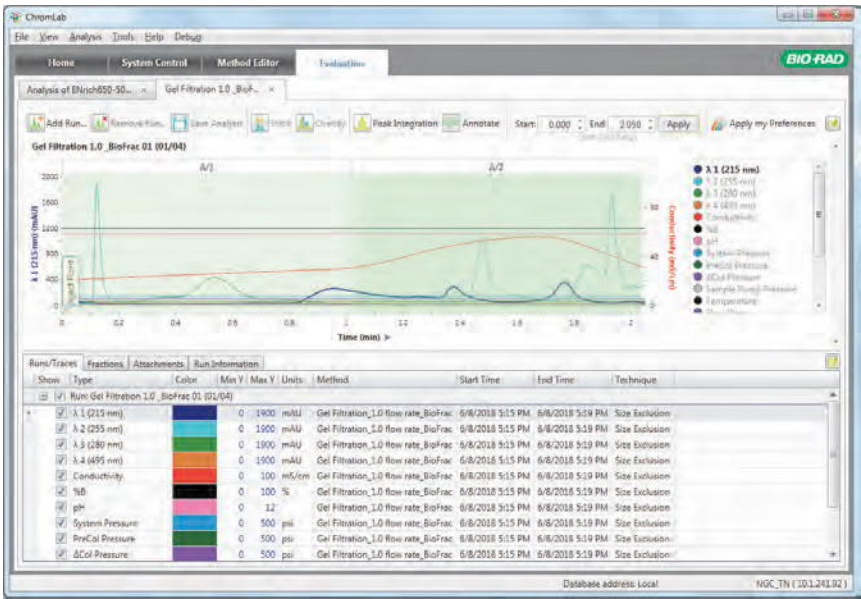
The Method Editor window enables you to create, open, review, edit, and run a method. You can also open and edit a method template to create a new template. Method Editor functionality is detailed in [Chapter 5, Method Editor](#). See also [Chapter 6, Creating a Method](#).



The Evaluation Window

The Evaluation Window

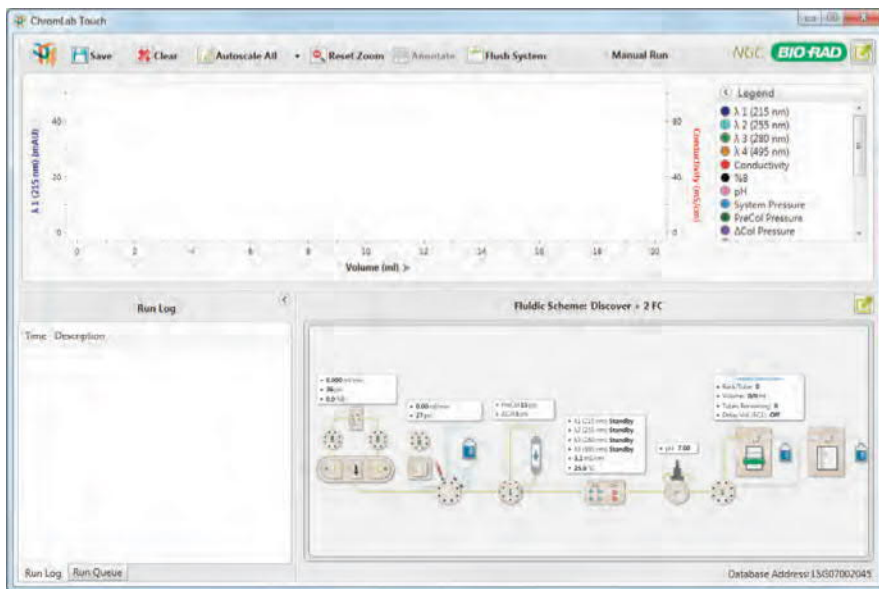
The Evaluation window enables you to view and compare run data, perform peak integration, and save run data as analyses. Evaluation functionality is detailed in Chapter 7, Evaluating Results.



## Instrument Control Touch Screen

In addition to ChromLab software running on a computer, the instrument is equipped with a touch screen that accesses system control functionality. You can use this touch screen to run, control, and monitor a run independent of ChromLab. See [System Control on page 33](#) for more information.

**Tip:** When the NGC system has been inactive for two hours the LED display screens on the instrument turn off, the touch screen dims, and a dialog box appears on the touch screen informing you that the system is in standby mode. You can take the system out of standby mode by touching OK in the dialog box, starting the system pumps by initiating a manual or method run, or clicking on a module in the fluidic scheme that has an LED display.



## Touch Screen Menu Commands

**Calibrate** — opens the Calibration dialog box, which displays instructions and settings for selecting a module and calibrating it. See [Calibrating a Module on page 74](#) for details.

**Point-to-Plumb** — starts the Point-to-Plumb feature and simultaneously turns off instrument LED lights so you can visually verify or change instrument plumbing. Displays the current fluidic scheme. See [Verifying Plumbing with the Point-to-Plumb Feature on page 77](#) for details.

**Change Fluidic Scheme** — opens the Fluidic Scheme Selector dialog box in which you can edit the fluidic scheme or choose another one. See [Fluidic Scheme Configurations on page 59](#) for details.

**Map Fluidic Scheme** — opens the Fluidic Scheme Mapping dialog box in which you can map devices on your instrument to their position in the fluidic scheme. See [Fluidic Scheme Mapping on page 70](#) for details.

**System Settings** — opens the System Settings dialog box in which you can customize system settings. See [System Settings on page 79](#) for more information about customizing your system.

**System Information** — opens the System Information dialog box, which lists the serial number and other general information about the NGC device as well as information about the system components, processes, and UV and UV/Vis detectors. From this dialog box, you can also set a static IP address for the system. See [System Information on page 102](#) for more details.

**Service** — for Bio-Rad technical service staff use only. Do not select this command.

**Help** — displays detailed information about touch screen menu commands.

**About** — displays ChromLab version and copyright information.

**Shut Down** — shuts down the NGC system, including the connected computer.

## Touch Screen Toolbar Commands

**Save** — saves in a data file the steps executed during a manual run.

**Clear** — deletes manual run data from the touch screen display.

**Autoscale** — automatically scales the chromatogram's primary y-axis to the tallest peak height during the run. Autoscaling is enabled by default.

**Reset Zoom** — resets the view to show the full chromatogram.

**Annotate** — adds a note to the chromatogram at points on the x-axis during a run or after the run completes.

**Flush System** — automatically starts a system flush run if the flush template selected in System Settings matches the current fluidic scheme.

**Note:** If a flush template has not been selected in System Settings, or if the selected template does not match the current fluidic scheme, clicking this command opens the templates dialog box from which you can select a system flush template to run.





## 3 System Control

The ChromLab System Control window is the main interface to the connected NGC chromatography system. This interface also appears on the system's touch screen. System Control settings enable you to perform a manual run, monitor and control a method run, verify the device plumbing with the Point-to-Plumb feature, control and calibrate the system, and map two or more valves of the same type on your instrument to their position in the fluidic scheme.

In the Home window, you can access the System Control window by selecting the System Control tab.

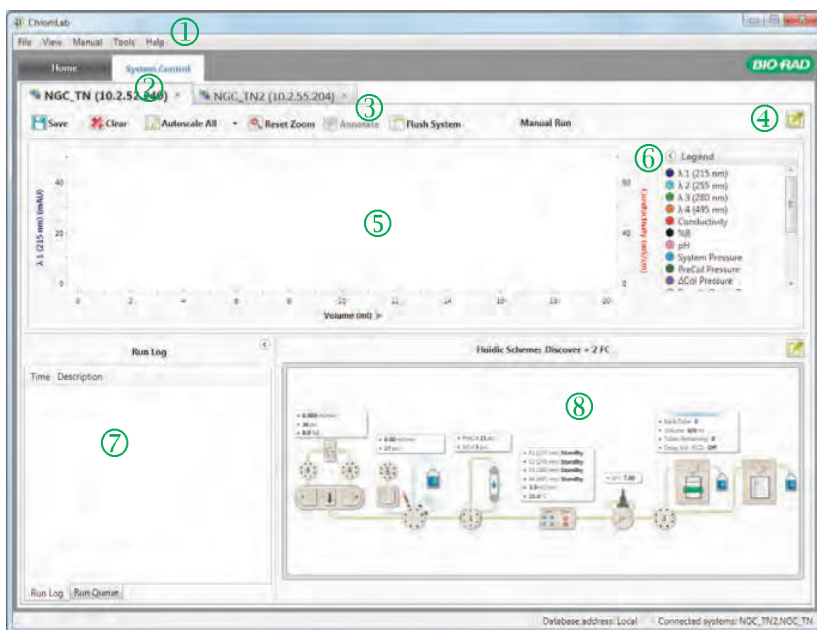
### System Control Window

The ChromLab computer can connect to multiple NGC systems and run methods on each system simultaneously. The System Control window displays a tab for each NGC system to which the ChromLab computer is connected. Each tab displays a chromatogram viewer and a graphical fluidic scheme. The chromatogram is a time-, volume-, or column volume-based view of the run data acquired from the instrument. The fluidic scheme is a real-time view of the instrument status and flow.

For enhanced viewing, you can maximize the chromatogram or the fluidic scheme using the Expand buttons on the right side of the window. This is especially useful for touch screen viewing.

## 3 | System Control

The fluidic scheme graphically depicts the flow between modules and how the system is configured and plumbed for an experiment. Each module's real-time status appears next to its image. For manual runs, a list of executed commands appears in the Run Log pane. In method mode, phases and steps of the method being run appear in their respective tabs, along with controls to stop or pause the run and hold the step. The Run Queue pane lists all the runs that are ready to be started and enables you to turn off the lamps after the runs are complete. The Run Queue pane is accessible in both manual and method modes.



## LEGEND

- 1 The menu bar provides quick access to File, View, Manual, Tools, and Help menu commands.
- 2 Tabs provide quick navigation among open windows (Home, System Control, Method Editor, and Evaluation).  
Tabs also provide quick access to each connected NGC system.

## System Control Window

### LEGEND

- 3 The tab toolbar provides commands to save the current run, delete manual run data from the display, autoscale the UV trace, change the chromatogram view, annotate the chromatogram, and flush the system using the system flush template selected in System Settings.
- 4 Expand buttons expand the selected pane to fill the screen.
- 5 The chromatogram viewer displays data acquired from the instrument as traces based on time, volume, or column volume.
- 6 The chromatogram legend matches each trace to its trace type and color and displays the wavelength value in nanometers for UV traces. You can view or hide traces by clicking them.
- 7 In method mode, run data appear in the Method Editor Phase and Step panes. In both modes, the Run Log pane presents a time-stamped record of run steps and events; the Run Queue pane lists runs that are waiting to start and enables you to turn off the lamps after the runs are complete.
- 8 The Fluidic Scheme pane depicts graphically how modules are configured and plumbed for an experiment.

## File Menu Commands

**Connect to System** — opens a dialog box that enables you to choose another NGC chromatography system to connect to. See [Connecting ChromLab Computers to NGC Systems on page 40](#) for more information.

**Disconnect System** — displays links which you use to disconnect ChromLab software from a connected NGC system or all connected NGC systems.

**Take Control** — opens a dialog box that enables you to take control of the NGC system from a connected user. This is useful in the event that the controlling computer is locked or the user performing a run is not available and there is an immediate need to stop the system.

**System Settings** — opens the System Settings dialog box in which you can customize system settings. See [System Settings on page 79](#) for more information about customizing your system.

**System Information** — opens the System Information dialog box, which lists the serial number and other general information about the NGC device as well as information about the system components, processes, and UV and UV/Vis detectors. See [System Information on page 102](#) for more information.

**Preferences** — opens dialog boxes in which you can do the following:

- Select pressure units for all system and software pressure values. This is a global setting. See [Units Tab on page 106](#) for more information.
- Set up an SMTP server to receive email messages about system notifications from the ChromLab computer. See [Email Server Setup Tab on page 107](#) for more information.
- Set default values for parameters used in new methods. The settings appear in the Method Settings window. See [Method Editor Tab on page 109](#) for more information.
- Create and configure a rack library for your fraction collectors. This is a global setting. See [Rack Library Tab on page 111](#) for more information.
- Set display preferences for the Evaluation window. See [Evaluation Tab on page 113](#) for more information.

**Exit** — closes ChromLab.

## View Menu Commands

**Show Chromatogram** — displays a chromatogram of the current run data. Clearing this command hides the chromatogram from view.

**Show Fluidics** — displays the fluidic scheme. Clearing this command hides the fluidic scheme from view.

## Manual Menu Commands

**Enter/Exit Manual Mode** — toggles ChromLab between manual and automatic modes.

**Save Recorded Manual Run** — in manual mode, saves in a data file the steps executed during a manual run.

**Clear Recorded Data** — deletes manual run data from the display.

## Tools Menu Commands

**Calibrate** — opens the Calibration dialog box, which displays instructions and settings for selecting a module and calibrating it. See [Calibrating a Module on page 74](#) for details.

**Point-to-Plumb** — starts the Point-to-Plumb feature and simultaneously turns off instrument LED lights so you can visually verify port locations during instrument plumbing. Displays the current fluidic scheme. Gray lines indicate the flow path. Clicking a line in the window turns on LED lights on the instrument corresponding to ports to be connected. See [Verifying Plumbing with the Point-to-Plumb Feature on page 77](#) for details.

**Change Fluidic Scheme** — opens the Fluidic Scheme Selector dialog box in which you can edit the fluidic scheme or choose another one. See [Fluidic Scheme Configurations on page 59](#) for details.

**Map Fluidic Scheme** — opens the Fluidic Scheme Mapping dialog box, which displays the location of two or more valves of the same type in the fluidic scheme, for instance two or more inlet valves or column-switching valves. You can use this dialog box to map the device on your instrument to its position in the fluidic scheme. See [Fluidic Scheme Mapping on page 70](#) for details.

**Flow Rate Converter** — opens the Flow Rate Converter tool, which enables you to determine the flow rate to use for each column in the method based on the column size and the initial rate entered. A rate entered in ml/min is converted to cm/h and L/h; a rate entered in cm/hr is converted to ml/min and L/h. You can copy the result in the converter and paste it into your method.

## Help Menu Commands

**Help** — displays screen-level help topics and links to installed manuals.

**Export Diagnostic Logs** — opens the Export Diagnostic Logs dialog box in which you can export all critical information that Bio-Rad Technical Support requires to diagnose issues. The log files and data are zipped and saved to a location that you choose. See [Exporting Diagnostic Logs on page 363](#) for more information.

**About** — displays version and copyright information about ChromLab software.

## Toolbar Commands

**Save** — saves in a data file steps executed during a manual run.

**Clear** — deletes manual run data from the display.

**Autoscale** — automatically scales the chromatogram's primary y-axis to the tallest peak height during the run. Autoscaling is enabled by default. When disabled, you can change the value of each individual UV trace. The Autoscale mode and the UV trace values are saved when you save the run.

**Reset Zoom** — resets the view to show the full chromatogram.

**Annotate** — adds a note to the chromatogram at points on the x-axis during a run or after the run completes.

**Flush System** — automatically starts a system flush run if the flush template selected in System Settings matches the current fluidic scheme.

**Note:** If a flush template has not been selected in System Settings, or if the selected template does not match the current fluidic scheme, clicking this command opens the templates dialog box from which you can select a system flush template to run. See [System Flush Tab on page 98](#) for more information.

## Context Menu Commands

### To access context menu commands

- ▶ Right-click in the chromatogram and choose a command from the menu that appears.

**Undo Zoom** — restores immediately previous zoom level.

**Reset Zoom** — resets the view to show the full chromatogram.

**Autoscale UV Trace** — automatically scales the primary y-axis to the tallest peak height during the run. While enabled, UV scale in the legend cannot be manually set. When disabled, you can change the value of each individual UV trace. The Autoscale mode and the UV trace values are saved when you save the run.

**Copy Chromatogram** — copies the chromatogram to the clipboard so you can paste it into another application.

**Save Chromatogram As** — saves the chromatogram in an image format you choose (.bmp, .gif, .jpeg, .png, or .tiff).

**Export as .csv** — exports run data as a .csv file, which can be opened in spreadsheet applications.

# **EXHIBIT 15**

**FILED UNDER SEAL**



**HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS’ EYES ONLY**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

CYTIVA SWEDEN AB, and GLOBAL LIFE  
SCIENCES SOLUTIONS USA LLC,

Plaintiffs

v.

BIO-RAD LABORATORIES, INC.,

Defendant.

C.A. No. 18-1899-CFC  
Consolidated

**DEMAND FOR JURY TRIAL**

**HIGHLY CONFIDENTIAL  
(TECHNICAL) – ATTORNEYS’ EYES  
ONLY**

**REBUTTAL EXPERT REPORT OF DR. BRUCE GALE**

**HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS’ EYES ONLY**

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**LIST OF REPORT EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
Exhibit 1	List of Materials Relied Upon
Exhibit 2	10.22.2014 Lundkvist Depo Tr.
Exhibit 3	Markman Hearing Transcript
Exhibit 4	NGC Chromatography System
Exhibit 5	(Filed Under Seal) BRGE00000846 - 864
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Exhibit 6	(Filed Under Seal) BRGE00000572 - 597
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Exhibit 10	(Filed Under Seal) BRGE00000623 - 654
Exhibit 11	(Filed Under Seal) BRGE00000785 - 826
Exhibit 12	(Filed Under Seal) BRGE00000655 - 688
Exhibit 13	(Filed Under Seal) BRGE00000714 - 747
Exhibit 14	(Filed Under Seal) BRGE00000689 - 713
Exhibit 15	(Filed Under Seal) BRGE00000477 - 510
Exhibit 16	(Filed Under Seal) BRGE00000748 - 784
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Exhibit 18	(Filed Under Seal) BRGE00002458
Exhibit 20	U.S. Publication No. 2008/0035542 (“Mourtada”)
Exhibit 21	U.S. Patent No. 5,766,460 (“Bergstrom”)
Exhibit 22	U.S. Publication No. 2008/0233653 (“Hess”)
Exhibit 23	06.26.2020 Lundkvist Depo Tr.
Exhibit 24	10.17.2014 Scandella Depo Tr.
Exhibit 25	Preliminary Injunction Hearing Declaration Images
Exhibit 26	08.17.2016 Soderman Depo Tr.
Exhibit 27	07.23.2020 Chapman Depo Tr.
Exhibit 28	06.24.2020 Hareland Depo Tr.
Exhibit 29	[REDACTED] BRGEDEL000610423 - 610434
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I, Bruce Gale, Ph.D., declare as follows:

**I. INTRODUCTION**

1. I have been retained by counsel for Defendants Bio-Rad Laboratories, Inc. (“Bio-Rad”) as an expert in the above captioned case. As part of this engagement, I have been asked to provide my opinions regarding U.S. Patent Nos. 9,709,589 (“the ‘589 patent”), 9,709,590 (“the ‘590 patent”), 9,709,591 (“the ‘591 patent”), 9,671,420 (“the ‘420 patent”), and RE47,124 (“the ‘124 patent”) (collectively, the “Asserted Patents” or “Patents-in-Suit”), specifically the validity of the Asserted Patents and whether or not the Bio-Rad NGC systems infringes the Asserted Patents.

2. I am being compensated at my usual hourly rate of \$500. I am being separately reimbursed for any out-of-pocket expenses. My compensation does not depend in any way on the outcome of this case or the particular testimony or opinions that I express. I have personal knowledge of the facts stated in this report, and I could and would competently testify to them if called upon to do so.

3. This report discusses my opinions with respect to the ‘589, ‘590, ‘591, ‘420, and ‘124 patents. In particular it is my opinion that the accused NGC systems do not infringe claims 1, 2, 4, 6-10, 12-17, 19-21, 23-27, and 30 of the ‘589 patent, claims 1-4, 10, 12-14, 17, and 18 of the ‘590 patent, claims 9, 14, 26, and 27 of the ‘591 patent, claims 1, 4-9, 15, 25, 27, 29, and 30 of the ‘420 patent, and claims 16, 19, 20, 22, 25, 27, 28, 30, and 33-35 of the ‘124 patent (“Asserted Claims”). This report also contains my responses to the Expert Reports of Dr. Steven Wereley and Mr. Nenad Vukicevic. These opinions, and the basis for these opinions, are set forth in full detail below. I also incorporate prior reports and declarations that I have submitted in this case and patent office proceedings.

**II. BASIS FOR OPINIONS**

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**A. Qualifications**

4. I fully incorporate herein by reference the qualifications disclosed in my opening report on invalidity.

**B. Materials Considered**

5. In forming the opinions set forth in this report, I have considered and relied upon my education, knowledge of the relevant fields, and experience. I have also reviewed and considered the Asserted Patents, their priority applications, and their prosecution file histories, the Court’s claim construction ruling and the expert report of Dr. Wereley as well as other materials expressly set forth in this report and identified in Ex. 1.

**C. Level of Ordinary Skill in the Art**

6. In my opinion, for the Asserted Patents, a person of ordinary skill in the art (“POSITA”) at the time of the invention would have a bachelor’s degree in Mechanical Engineering, Bioengineering, or Electrical Engineering and three years of fluid handling machine design experience, or would have an advanced degree in a similar field with at least one year of related design experience. This is the same level of experience that I proposed in my report on invalidity.

**III. LEGAL STANDARDS**

7. I am not a legal expert and offer no legal opinions. However, I have been informed by counsel of the following legal standards that apply to the pertinent technical issues, and I have applied those standards where appropriate in arriving at my conclusions expressed in this declaration.

**A. Non-Infringement**

8. I understand that when considering whether a person or entity infringes the asserted claims, each of the asserted claims must be considered individually, and to establish

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infringement of a patent, all of the elements of at least one of the asserted claims must be present, either literally or by an equivalent.

9. I understand that there are independent claims and dependent claims. An independent claim is read separately to determine its scope. A dependent claim is one that is based on an independent claim. To determine the scope of the dependent claim, I understand that it must be read to include all the elements of the claim(s) from which it depends, together with the additional limitations contained in the dependent claim.

**1. Literal**

10. I understand that Cytiva bears the burden of proving by a preponderance of the evidence that Bio-Rad infringes the Asserted Claims. I have been informed that analysis of patent infringement requires two steps. The first step is to properly construe the patent claims, which is a step taken by the Court. The second step is to apply the construed claims to the accused product on an element-by-element basis. A patent claim cannot be “literally” infringed if each and every claim element is not found in the accused product. In other words, if one element is not satisfied, the claim is not infringed. If an independent claim is not infringed, I understand that a claim depending from the independent claim, which must have all the elements of the independent claim, also is not infringed.

11. I have interpreted the claims from the perspective of a person having ordinary skill in the art and have interpreted them in light of the Court’s claim construction, the specification and the prosecution file history and any relevant extrinsic evidence.

**2. Doctrine of Equivalents**

12. I understand from Dr. Wereley’s report on infringement ¶ 17, that neither he nor the Plaintiff are relying on the doctrine of equivalents, so I will not discuss it in my report.

**3. Prosecution History**

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13. I understand that a patent owner is prevented from recapturing what had been surrendered during prosecution to obtain allowance of the claims. I understand that the claims of the patent cannot be interpreted to cover subject matter that the patent owner argued to the U.S. Patent Office was beyond the scope of the claims. I have been informed that estoppel arises when an amendment or argument is made to secure the patent and the amendment or argument narrows the patent’s scope.

14. I have also been informed that estoppel arises only where the patentee clearly and unambiguously disavowed claim scope.

**4. Indirect Infringement**

15. I have been informed that an accused infringer may induce or contribute to the infringement of a claim by either: a) encouraging a party to take steps knowing that the acts they induced constitute patent infringement and the encouraging acts actually resulted in patent infringement or b) selling or importing into the United States a component of a patented machine manufacture, combination or composition or a material or an apparatus for use in practicing a patented process, which constitutes a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and the component is not a staple article or commodity of commerce suitable for substantial non-infringing use.

**IV. THE ASSERTED PATENTS**

16. I fully incorporate herein by reference the discussion of the Asserted Patents, their prosecution histories, and Cytiva’s alleged conception and reduction to practice disclosed in my opening report.

17. Overall, as outlined in my opening report, liquid chromatography and modularity are nothing novel to the asserted patents. Not only do the Metrohm and Applikon systems

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discussed in my opening report demonstrate this, Bio-Rad’s own DuoFlow prior art system does as well. The main difference between the DuoFlow, which was a modular system where the modules are stackable, and the NGC, which is a modular system in which the modules slide into slots in a housing, is the form factor and space. This difference is analogous to the difference between a stereo system (DuoFlow) and a card catalog (NGC). Both forms of modularity allow users to replace individual modules or add additional modules to the systems. But just like a card catalogue, or an Ikea dresser that has a housing and slots to insert individual drawers, there is nothing new or novel about the idea of using a single housing that can accommodate multiple individual components.

18. I do not see anything in the specification of the asserted patents or in Dr. Wereley’s report, for example at paragraphs 23-30, that describes the inventors of the asserted patents as having invented any new chromatography function or process. What I mean by this is that the patents do not claim to perform chromatography in some new and different way. Ex. 2 Oct. 22, 2014 Lundkvist Depo. 88:2-90:7. Rather, the patents are directed at using past methods and components with those components simply arranged in a particular manner, *e.g.*, as interchangeable units with the electronics section of the unit on one side of a panel member and inside the housing, and the fluidics section of the unit on the other side of the panel member and outside the housing. Thus, at most, the patents claim a different form factor, one in which modularity is achieved using a single housing like a card catalogue or Ikea dresser, rather than using stackable boxes like old stereo. But this form factor is not new or novel regardless of what type of application it is applied to.

19. Liquid chromatography systems are just a tool scientists use in their research. Accordingly, what scientists’ value most in a chromatography system is that it be capable of

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performing the specific chromatography techniques they require in order to, for example, purify proteins for use in their research. The specific form factor, or the form of modularity that the system employs is secondary, at best, in a user’s assessment of what liquid chromatography system will be capable of satisfying their needs. A user will never buy a system that is not able to perform the chromatography techniques required. In other words, function is far more important than form to a user of liquid chromatography systems. As I stated above, the patents in suit are not directed to performing any new aspect of chromatography or performing any existing aspect of chromatography in any new way. Rather the patents are simply directed to form factor or aesthetic aspects of chromatography. The machine is likely to ship more easily as a single unit rather than as multiple boxes. But I do not consider this to be any type of technological advance.

**V. CLAIM CONSTRUCTION**

20. I understand that the Court has entered a Claim Construction Order.<sup>1</sup>

21. I understand that the parties agreed on the following constructions relevant to the Asserted Patents discussed in this report.

<b>Terms</b>	<b>Agreed Construction</b>
“CPU” / “CPU unit”	“central processing unit”
“the fluidics section is external to the housing and the non[-]fluidics section is internal to the housing”	“the fluidics section is on the outside of the housing and the non-fluidics section is on the inside of the housing”

22. I understand that the Court has construed the disputed terms as follows.

<b>Terms</b>	<b>Court’s Claim Construction</b>
“interchangeable modular component”	“component that can be inserted into and removed from positions in the housing and that has a standardized size and shape that allows it to be exchanged with another component”
“interchangeable modular fluid	“fluid handling unit that can be inserted into and

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<sup>1</sup> D.I. 89.

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handling unit”	removed from positions in the housing and that has a standardized size and shape that allows it to be exchanged with another fluid handling unit”
Claim Preambles (“An automated liquid chromatography system comprising” / “A method of modifying a fluid flow path in an automated liquid chromatography system comprising” / “A method for building an automated liquid chromatography system, the method comprising”/ “A liquid chromatography system arranged to provide a controlled fluid flow through a chromatography column, the system comprising”)	The preambles are claim limitations.
“liquid chromatography system”	Plain and ordinary meaning
“automated liquid chromatography system”	Plain and ordinary meaning
“wherein the system is capable of performing automated liquid chromatography”	Plain and ordinary meaning
“non-fluidics section” / “non-fluidics section” / “non fluidics section”	“a section of the interchangeable fluid handling unit that includes electrical components and does not include fluidics components”
“a fluid handling section” / “a fluidics section”	“a section of the interchangeable fluid handling unit that includes fluidics components and does not include non-fluidics components”

23. In all cases, I applied the agreed claim constructions or the Court’s constructions as one of ordinary skill in the art would interpret them in light of the specification and the file history in performing my analyses and rendering my opinions in this report.

24. In this regard, it is my opinion that Dr. Wereley has misconstrued the Court’s claim construction at least with respect to the terms fluidics section and non-fluidics section in Paragraphs 57-58 of his report. He has done so, apparently, because he did not state in his opening report that he reviewed the file history where the inventors of the asserted patents made certain statements explaining what their inventions were not. By failing to review those statements, Dr. Wereley interprets the Court’s claim construction (and statements made during

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the hearing that are not part of the claim construction) in a way which is inconsistent with the inventors’ statements during the prosecution. I will address these issue more particularly with respect to certain elements but address them here in a general manner as well.

25. Dr. Wereley quotes isolated portions of what I understand to be the hearing transcript from the claim construction proceedings to claim that there can be non-fluidics (electronics) outside the non-fluidics section of each module. (Wereley Report ¶57). But what the portion of the hearing transcript that Dr. Wereley quoted did not say is that electronics of the module can be in the fluidics section, even if they are not in the non-fluidics section. Ex. 3, Markman Hearing Tr., 97:16-25. All it says is that it may be possible for there to be electronics that are not in the fluidics section that are also not in a non-fluidics section. *Id.* That does not mean that once can indiscriminately define electrical components as being in some section that is neither a fluidics section or a non-fluidics section for purposes of establishing infringement. By failing to review the file history and see how the inventors interpreted what a “section” is, Dr. Wereley is interpreting the claims and asserting infringement against the Bio-Rad devices in ways that are inconsistent with the word section in the asserted patents and the representations the inventors made to the patent office to obtain their patent. By doing so, Dr. Wereley is also interpreting the random passages he was presented from the claim construction hearing in an improper way.

26. For example, the judge stated at pages 90-91 of the hearing transcript after counsel went through some, but not even all, the statements in the file history that the inventors made to obtain their claims that there was clear and unmistakable representations by the inventors that the electrical components should be separated from the fluidic components:



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6 THE COURT: -- I think Mr. Bilsker makes a  
7 compelling argument that looks pretty clearly and  
8 unequivocally, your client, or the applicant for the patent  
9 I should say made clear, clearly and unequivocally, as far  
10 as I'm concerned, that there are two sections, and that's  
11 what differentiates this patent from Bergstrom and Hess. So  
12 why don't you walk me through your response to that.

13 MR. MILLER: Okay. So, first of all, I think  
14 it's important to note that we don't disagree that there's  
15 going to be a separation from the fluidics section and  
16 non-fluidics section, but, first of all, there can be other  
17 sections.

18 As you pointed out, the claim language talks  
19 about a fluidics section and a non-fluidics section, and all  
20 the claims use the transitional phrase comprising, which  
21 means there can be other sections.

22 So even if you draw the circle --

23 THE COURT: That wasn't how you distinguished  
24 Bergstrom and Hess. I mean, you pretty explicitly said to  
25 the Examiner, hey, what makes this different is we've got

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1 complete separation of the fluidic and the non-fluidic  
2 section. And, incidentally, I think that's consistent with,  
3 you know, your slide, which says, hey, the phrase itself  
4 tells you, there's no fluidic component in the non-fluidic  
5 section.

6 MR. MILLER: Well, our argument on non-fluidics  
7 in the fluidics section, that's what I called the  
8 non-fluidics section.

9 THE COURT: As opposed to the fluidics section.  
10 I mean, it's a referential definition. Right? It says,  
11 this is a non-fluidics section as opposed to the fluidics  
12 section.

27.

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28. The Court then reiterated at pages 102-103 of the hearing transcript, the clear and unequivocal statements that the inventors had made to obtain their patents and about there needing to be two sections: a fluidics section and a non fluidics section and there had to be complete separation between the fluidics and the electronics in them:

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18 I'm going to interpret non-fluidics section to  
19 mean, "a section of the interchangeable fluid handling unit  
20 that includes electrical components and does not include  
21 fluidics components."

22 I'm going to construe a fluid handling section  
23 to mean, "a section of the interchangeable fluid handling  
24 unit that includes fluidics components and does not include  
25 non-fluidics components." And that seems to me to be the

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1 most reasonable construction. That is consistent with what  
2 I think were clear and unequivocal statements to distinguish  
3 this patent from Bergstrom and Hess, because the basis of  
4 the distinctions to the Patent Examiner were that this  
5 patent had two sections that, at least two sections, one is  
6 non-fluidic, one is fluidic, that are separated completely  
7 and that do not contain components of the other section.

8 That does not, however, preclude the possibility  
9 that there are other sections that are in the invention, and  
10 that's important because that is consistent with the use of  
11 the indefinite article, which is inconsistent with Bio-Rad's  
12 insistence that "all," either fluidic or non-fluidic  
13 components, are in the respective handling unit.

14 So that actually seems to me is the right result  
15 in this case and I'm going to construe then these last group  
16 of terms in that manner.

29.

17 All right. To those questions, the answer is

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30. Again, just because there is a theoretical possibility that there may be yet a third or forth section where there could be an electrical or fluidic component, does not mean that any component that is encountered that is inconsistent with an infringement theory can be dealt with by claiming it is in a “section” that is distinct from what is otherwise a fluidics or non fluidics section. Any creation of this alternative additional section that is inconsistent with how the inventors construed the prior art is not permissible and Dr. Wereley failed to consider that in any way in his opening report.

31. I note that relevant portions of the file history that inform that a section cannot be defined as Dr. Wereley has tried to do in his infringement report appear as Ex. G in the joint claim construction briefing which I understand has the Document number DI 52-8 (Ex. 19)<sup>2</sup>. I will be referring to pages from that Exhibit G, which I incorporate into this report as well as the Mortada, Ex. 20, Bergstrom Ex. 21, and Hess Ex. 22 references discussed in those pages of the File History. I will also refer, when necessary to the slides that counsel used during the claim construction hearing to illustrate points from the File History.

**VI. SUMMARY OF OPINIONS**

32. As set forth in detail below, based on my review of the Asserted Patents, including the Asserted Claims and the prosecution histories of the Asserted Patents, the claim constructions in this matter, the accused products and functionality the Wereley and Vukicevic Reports, and the materials listed in Exhibit 1, I have reached the following opinions:

- The accused products do not directly or indirectly infringe, any asserted claim of the ’420 patent;
- The accused products do not directly or indirectly infringe, any asserted claim of the ’589 patent;

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<sup>2</sup> For clarity, I refer to the original exhibit identification Exhibit G throughout. But Exhibit G is Exhibit 19 here.

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- The accused products do not directly or indirectly infringe, any asserted claim of the ’590 patent;
- The accused products do not directly or indirectly infringe, any asserted claim of the ’591 patent;
- The accused products do not directly or indirectly infringe, any asserted claim of the ’124 patent;
- Dr. Wereley and Mr. Vukicevic have failed to identify how the accused products meet each and every limitation of any Asserted Claim sufficient to establish infringement;
- Even if Dr. Wereley and Mr. Vukicevic assertions regarding infringement were correct, which they are not, there are non-infringing alternatives available to Bio-Rad; and
- Last with respect to licenses that may provide a basis for determining a reasonable royalty because they are directed to comparable technology, I have analyzed a number of agreements and provided an opinion for how the technology in those licenses is similar to the technology in the assert patents.

33. In the following sections, I provide a narrative of my opinions.

**VII. OVERVIEW OF THE ACCUSED PRODUCTS**

34. The NGC system is a liquid handling system that functions in essentially the same as the prior DuoFlow system. The only real difference is the form factor in the way the components are arranged. The system includes modules with both electrical and liquid components. In all the NGC modules, there are electrical components that are not on either side of a panel member and are thus not separated from the fluidics components as required by the claims. For the same reasons, all the modules have electrical components that sit beside fluidic components and are not on either side of the liquid handling panel and are not internal to the housing as required by the claims. Those components are therefore in the fluidics section. Because of this arrangement, the NGC instrument fails to meet multiple elements of the claims and one of the primary requirements goals of the asserted patents, to separate the electrical and



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fluidic components of the modules by having them on either side of at least two different panels (the panel member and the liquid handling panel).

**VIII. NON-INFRINGEMENT OF THE ASSERTED PATENTS**

35. Based on my analysis of the Asserted Claims as well as an analysis of the accused products and functionalities it is my opinion that Bio-Rad does not directly or indirectly infringe, the Asserted Claims. Below, I address the elements that are lacking in the accused products.

**A. Non-Infringement of the ’420 Patent**

**1. Element [1.e]: “an external fluidics section”**

36. Element [1.e]<sup>3</sup> of the ’420 patent requires “an external fluidics section.” As the court defined it, a “fluidics section” means: **“a section of the interchangeable fluid handling unit that includes fluidics components and does not include non-fluidics components.”**

While the Court did not construe the term “external” I understand it to mean external to the housing. This is consistent with other elements and phrases of the claim such as the first wherein clause of claim 1 of the ’420 patent which states that when the interchangeable modular components are inserted into the housing the fluidics section is external to the housing and the non fluidic section is internal to the housing. *See* ’420 patent, Claim 1 at Col. 9:28-34.

37. At paragraphs 105-119 of his report, Dr. Wereley argues that four different configurations of the Bio-Rad NGC machine, the 1) Quest, 2) Scout, 3) Discover and 4) Discover Pro (*See* Dr. Wereley at paragraphs 93-96 identifying various components in each of these four systems to satisfy element 1(d) “three or more fluid handling units arranged as interchangeable modular components comprising”)

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<sup>3</sup> For convenience and consistency, I refer to the elements using the same nomenclature as Dr. Wereley.

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38. Dr. Wereley then selects two system pumps and a sample injection valve that he finds present in each of these modules satisfy element 1(e). *See* Wereley at ¶105-114. Dr. Wereley states the components satisfy the element because, among other things, the specifications for each of the modules state that [REDACTED] *Id.* at ¶ 107.

39. Dr. Wereley then goes on to cite to images of NGC pump modules and a sample inject valve module and then purportedly illustrates the components that define the external fluidics section on those modules. *See Id.* at ¶ 110, 112, 113. He states that the portions he has illustrated/identified are all involved in the transmission of fluidics, *e.g.*, tubing, flow cells and outputs etc. *Id.* at ¶ 115.

40. While recognizing that each of them modules have electronics visible to the user and outside the housing, Dr. Wereley states in conclusory fashion, without any analysis, including without any reference to statements the inventors made during the prosecution to obtain their patents, that “[a] POSITA would recognize that externally located non-fluidics components in Bio-Rad’s NGC system are not a part of the claimed fluidics section.” *Id.* at ¶116. I disagree. From what Dr. Wereley has presented in his opening report, there is no way for one of ordinary skill in the art to draw that conclusion other than *ipse dixit*.

41. What I mean by that is that Dr. Wereley has identified nothing in his opening report that would provide any guidance to one of skill in the art on how a “section”, whether fluidics or non-fluidics, is to be defined in the asserted patents. The failure of analysis and facts results in a lack of proof on this element and Dr. Wereley having failed to meet his burden of proof in this report.

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42. Moreover, when one of ordinary skill in the art performs an analysis of the patent, the statements the inventors made to obtain their patents, and the actual modules that have been accused, they would only be able to come to the conclusion that there is no external fluidics section in the two pump and one injection valve module that Dr. Wereley has relied on to prove infringement of this element.

43. Throughout the specification of the asserted patents, the inventors stress that there needs to be separation of fluidics and electronics components to ensure that electronics are not harmed when changing fluid connections and when a leak occurs. *See, e.g.*, Col. 2: 28-32 (a liquid handling panel to separate fluidics and electronics); Col 6: 17-620 (in one embodiment, the panel member essentially separates the fluidics section from the electronics and internal electronics); Col. 6: 10-29 (noting various arrangements, including with and without a panel member such that the electronics are separated from the fluidics through the use of such components as a suitable sealing arrangement between the housing opening and the external fluidics side of the module); Col. 7:7-25 (noting air tight sealing between the component positions and the non fluidics section and noting configurations, such as that claimed, where fluids are strictly on one side of the fluid handling panel and the electronics are strictly on the other: “According to one embodiment, fluids are strictly restricted to the fluidics section 30 of the interchangeable modular components 26, but in alternative embodiments, only fluid connections are restricted to the fluidics section 30 allowing fluid to “cross” the fluid handling panel inside the non-fluidics section 30 of the interchangeable modular component 26.”)

44. I note that nowhere in the patent is there a description of anything other than two sections in a module, a fluidics section and a non-fluidics section. To the extent there is some other intermediate section, it is nowhere described in the patents or how to determine it.



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Nonetheless, even if one of skill in the art were to assume that such a section could exist, they would recognize that such a section would need to satisfy the goals of the invention, which is to keep the fluids separate from the electronics. Dr. Wereley never considered this requirement, which is present not only in the passages cited above, but also by the named inventor Mr. Lundkvist, Cytiva’s previous expert, Dr. Scandella, and statements that the inventors made during prosecution to obtain the patents.

45. For example, the named inventor Mr. Lundkvist testified: “If it can get liquid on the electrical component, it will not be our concept. . . So –in our concept it, has to be separated with a sealing, those two parts – the liquid and the electrical stuff.” Ex. 2, 10/17/14 Dep at 141:14-19.

14 And it was important to separate the  
15 fluidic section from the electrical components,  
16 such as circuit boards, because the front side  
17 where they have the flow path, the -- customer  
18 handled it with the finger -- finger tights --  
19 when you screw it in, the valve, for example?  
20 When you have the customer not have  
21 mounted it in the proper way, they can maybe get  
22 loose and spraying all around with the liquid?  
23 And it's important to protect that  
24 leakage so it won't go in the electrical circuit  
25 board, so -- the electrical component.

46.

47. Ex. 2, 10/17/2014 Lundkvis Dep. At 140:6-25.

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11 Q. So it would not be your concept if you  
12 had electrical components on the front within  
13 the flow path?  
14 A. If it can get liquid on the electrical  
15 component, it will not be our concept.  
16 Q. Okay.  
17 A. So -- in our concept it, has to be  
18 separated with a sealing, those two parts -- the  
48. 19 liquid and the electrical stuff.

49. Ex. 2, 10/17/2014 Lundkvis Dep at 141:11-19.

20 Q. So you can't -- based on what you said  
21 before, you don't want -- also based on what  
22 your patent says -- you say that the electrical  
23 components -- the circuit boards, the motors,  
24 the pH sensor, the UV sensor --  
25 A. Yeah.

1 LUNDKVIS  
2 Q. -- all need to be inside the housing  
3 in that non-fluidic section, right?  
4 A. I'm referring to the concept again.  
5 It's just important to separate those  
6 with a sealing?  
7 And if it's outside or inside, it  
8 doesn't matter for the concept.  
9 Yes, if it's sealed off, that's very  
10 important, so it won't -- they won't  
11 interfere -- the liquid won't interfere -- let  
50. 12 it come down to the electric circuit board.

51. Ex. 2, 10/17/2014 Lundkvis Dep at 144:20 – 145:12.

52. In fact, Mr. Lundkvist testified that the separation was so important and central to his invention that he did not consider a system in which the fluidics and electronics were not

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separated as something that he had invented. Ex. 23, 06/26/2020 Lundkvis Dep at 151:24-155:15

6 Is fair to say that if a system  
7 does not require the fluidic components to  
8 be separated from the electrical components,  
9 is it fair to say that such a system is not  
10 what you consider to be your idea or your  
11 invention?  
12 MR. NISHIMOTO: Objection, form.  
13 A. Yes, my idea was to have a -- a  
14 wall to separate these, the fluidics, from  
15 the electronics, yes.

53.

54. Ex. 23, 06/26/2020 Lundkvis Dep at 151:24-155:15 (only 155:6-15 reproduced here).

55. Plaintiffs’ first expert similarly identified the importance of the separation of electronics and fluidics to the invention at pages 54-56 of his deposition reproduced below:

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17 saw.  
15 Q What's the purpose of this invention, as 10:39:56  
16 you understand it, that's described in the '718  
17 patent?  
18 A Well, as I see it, this invention allows  
19 the user to have greater flexibility in terms of how  
20 he uses his -- his fluidics handling system, and in 10:40:12  
21 terms of the different types of applications that  
22 can be used, and in terms of easily reconfiguring  
23 the system to accommodate new uses and possibly new  
24 environments where the machine is used.  
25 Q What's the reason for separating the 10:40:34  
Page 54

1 fluidics sections from the electrical components?  
2 A Well, one reason is to protect the  
3 electrical components. The electrical components  
4 typically are sensitive and easily damaged by  
5 contact with -- with fluids, particularly the kinds 10:40:53  
6 of fluids that are used in the fluidics section.  
7 Q Any other reason?  
8 A Probably other reasons. One -- one reason  
9 is to make it easier to contain it, to control the  
10 environment of the electronics components. 10:41:10  
11 Q Anything else?  
12 A There -- if you let me think for a minute,  
13 I could come up with some more.  
14 Q Go ahead.  
15 A But those are -- 10:41:24  
16 Q Go ahead and think.  
17 A Well, another is that in a laboratory  
18 environment, one is -- solutions are constantly  
19 getting splashed around when they don't -- when you  
20 don't intend them to be. A piece of tubing breaks 10:41:35  
21 or pops off of a fitting, or a beaker tips over and  
22 you end up with -- with salt solution splashed on  
23 the front of your instrument. These are the kinds  
24 of things that happen in the lab, and that an  
25 instrument -- instrument such as these automated 10:41:52  
Page 55

56.

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57. 

1 liquid handling systems, you'd like them to be able 2 to cope with that.
---

 EX.

58. Over and over again during the prosecution of the applications that lead to the patents and in order to distinguish their invention over the prior art, the inventors relied on and pointed to the same need for separation of fluidics and electronics in their invention to ensure that the electronics would not become wet and therefore likely damaged. For example, when addressing and distinguishing the Mourtada reference from their invention, the inventors stated: “The reason for separating the fluidic and non-fluidic sections is to stop the non fluidic sections getting wet when pipes etc. are reconfigured on the machine, and/or when the modular components are rearranged. None of those features are disclosed in or obvious from Mourtada ... The apparatus as proposed in claim 1 thus provides the unexpected advantage that not only can component positions be reconfigured easily and thereby simplify the fluidic interconnection of the components used, but alternatively, fluidic reconfiguration can be carried out without precious electrical parts becoming wet or contaminated. This is particularly advantageous where toxic or corrosive, or pathogenic liquids are being handled. On the one hand the organisation of the components can be optimised, and they can be protected in use. These advantages are not present in Mourtada or any prior art cited.” Ex. G at GEHC 001477- 1478. (emphasis added)

59. With respect to the Bergstrom prior art the inventors were distinguishing they stated: “Applicants submit that Bergstrom has given no thought to what happens when one unplugs a module and gets the electrical contacts 19 wet which will be inevitable since the contacts 19 appear to be housed in the cup shaped aperture 14, or what happens to the processor 55 in Figure 10 when that gets wet. *Id.* at GEHC 001451.



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60. The inventors said the separation requirement was even more important in liquid chromatography systems as opposed to other automated fluid handling systems: “The features of claim 17 as applied to liquid chromatography are particularly advantageous because such a system is typically used for many different initial experiments to prove the principles for larger scale operations. In such use, the system components are frequently reconfigured and in so doing the advantages of fluid and non-fluid separation, as claimed in claim 17 become even more significant, for example by providing a housing for liquid chromatography components including a liquid handling panel for accepting the components and avoiding contamination of electrical components.” Ex. G at GEHC 001418.

61. To ensure that the goals of the invention were met, the inventors described in great detail during the prosecution when they were distinguishing the prior art what was necessary to separate the fluidics from the non-fluidics sections and what would not be considered separation – something that still had a likelihood of the electronic components of a module becoming wet when fluid connections were changed, modules were rearranged, or a leak occurred. If that was possible, then one of skill in the art would recognize that the fluidics and the non fluidics (electronics) were not in distinct sections that were separated. Rather they would be in the same section.

62. And as will be explained in more detail in the following paragraphs that is what is present in the Bio-Rad accused modules. One of ordinary skill in the art reading the file history would only be able to come to the conclusion that the external electronics that Dr. Wereley recognizes are present in the accused Bio-Rad modules (the two pumps and injection valve, Wereley ¶ 116) are not in sections that are distinct from the fluidics sections. Rather, they are in the same section and not separated in the manner the inventors said they needed to be to be part

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of the invention and distinct from the prior art. For example, the accused pump module has switches, a display, and LED lights which the user sees, as well as a PCB and ribbon electrical connector in the overlay. *See e.g.*, Wereley ¶ 142, showing pictures of accused pumps in Ex. 48, 49 and ¶ 150 quoting from manual Ex. 47 stating that there are switches on the exterior of the pump modules. *See also* Ex. 25.

63. In particular, the inventors pointed out that for there to be separation of the electrical components and the fluidic components of a module such that they were in separate sections and unlikely to have fouling/wetting or contamination of the electrical components if there was a leak of the fluidic components, there had to be a particular spatial relationship between the components.

64. In particular, the inventors said multiple times that the fluidics and the electronic components of a module need to be on opposite sides of a panel for a) them to be separated, b) to ensure that the electronics would not get wet if there was a leak, and c) to define the electronics and the fluidics as being in separate sections. In discussing Bergstrom, the inventors said: “The modules of Bergstrom do not separate their fluidic and electrical parts (where they have electrical parts). Further, those paths cross into the base plate at about the same region. The detector module 10 of Figure 10 illustrates that **fluid and electrical parts are adjacent, not on either side of a panel.** Ex. G at GEHC 001451.

65. After stating that Bergstrom gives no thought to making sure that electrical parts do not get wet, which I cited to above, the inventors then reemphasize, one paragraph later, the separation point and again state that the fluidic and electronic parts need to be on opposite sides of a panel in the invention. In fact they not only state that the electronic parts in a modules need to be on opposite sides of one panel, but on opposite sides of two different panels : “These

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problems in the Bergstrom design are not addressed in Burger, but are cleverly addressed in presently claimed invention **by separating** the fluidic and non fluidic parts of fluid handling units **across a fluid handling panel** and **across a panel member of the modular components,** **which inhibits the problems mentioned immediately above.”** *Id.*

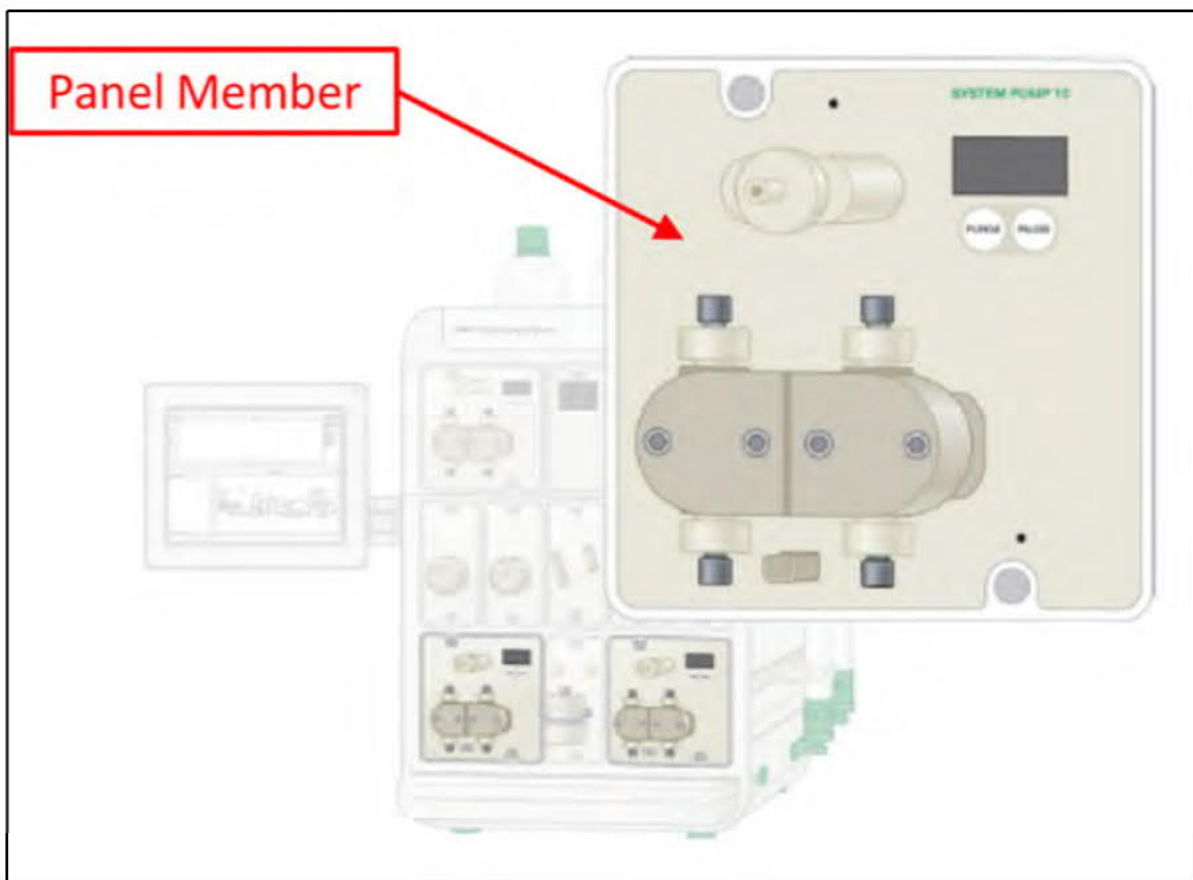
66. The accused modules do not meet those requirements for multiple reasons and therefore do not have external fluidics sections, ones that do not have electrical components, for multiple reasons.

67. First, having failed to refer to any of the File History statements which require the fluidics components of a module to be separated from the electrical components by at least two different panels to be considered by one of ordinary skill in the art to have distinct fluidics and electronics sections, Dr. Wereley provides no detailed analysis of the alleged panel member of the modules that are supposed to separate fluidics from electronics components of a module to meet the requirement that the electronics and fluidics are in separate sections.

68. Dr. Wereley purports to analyze the panel member as claim element 1(h) at paragraphs 138- 147. But the analysis is cursory and conclusory again. At paragraphs 139 and 141, Dr. Wereley pastes pictures of a Bio-Rad system pump and a sample inject valve and simply draws a red arrow and red box and concludes these are the panel members of the modules. I reproduce those figures below:



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69.

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70.

71. At paragraph 145, Dr. Wereley cites to testimony from two Bio-Rad witnesses to establish that what he has pointed to is a panel member. But, the testimony does not do so. Both Mr. Bland, and Mr. Chapman, whose testimony is quoted, state that the component that Dr.

Wereley points to as the panel member is actually two separate parts: there is 1) “a front plate”

and an “overlay” *Id.* at ¶ 145. Mr. Chapman testified that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. *Id.* at p. 91

(quoting Chapman testimony).

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72. In other words, Mr. Chapman’s testimony makes clear that the faceplate is what is responsible for allowing the module to be mounted on the instrument housing. I have confirmed this by holding and physically examining a number of the Bio-Rad modules. The specification of the asserted patents describes the panel member as the structure that is used to attach the module to a component position in the in the liquid handling panel. *See e.g.*, ’420 patent Col. 6:30-34 (“As is disclosed in FIGS. 4a to 4d, the interchangeable modular components 26 comprises a panel member arranged to separate the fluidics section from the non fluidics section and for attachment to a component position in the liquid handling panel.”)

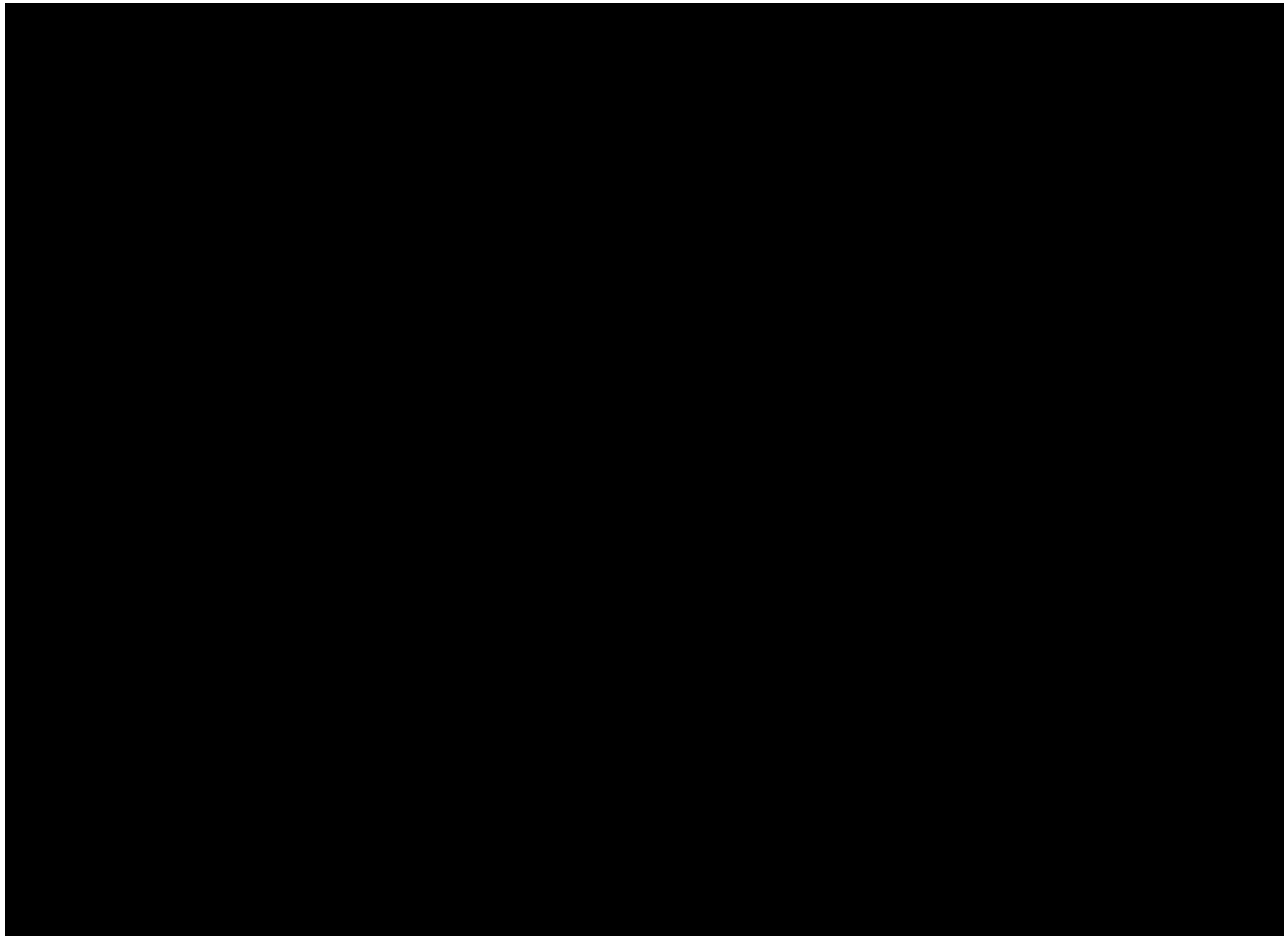
73. The first problem with Dr. Wereley’s analysis is that he equates two distinct parts, the face plate and the overlay and calls them collectively the panel member. *See* Wereley at ¶ 146, referring to the “face plate/overly structure” The assembly drawing from one exemplary module, [REDACTED]

[REDACTED]

[REDACTED]

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74.



Ex. 6, BRGE00000582.

75.



76.



One can see from the figure that the overlay is full of electronics. There is a printed circuit board which appears brown or copper colored.

There is a ribbon wire connector, and there are LED lights shown on this module. Other modules also have a display that the user can see as well as switches for the user to activate. The

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LED lights, the display and the switches are not trivial elements added to avoid infringement as I understand plaintiff’s counsel portrays them. Rather the LED lights tell a user where to make fluidic connections and the display enables users to easily see values and parameters on the modules. [REDACTED]

[REDACTED] Even Plaintiffs’ witnesses Mr. Soderman testified that the LEDs are useful Ex. 26, 115-116 (“Q: What do you think about those small LED lamps? A. Good to have for a beginner.”) and Bio-Ra employees have pointed out that it is a feature which users like and appreciate. Ex. 27, Chapman Depo Tr. at 206:21-207:13.

77. In any event, given that the overlay and faceplate are two separate structures held together by a few drops of glue, one of ordinary skill in the art would not consider them collectively the panel member.

78. But, even if one of ordinary skill in the art reading the specification considered the overlay and faceplate to be the panel member, they would not consider the electronics that are part of the overlay to be in a separate section of the module from the fluidics section as Dr. Wereley concludes with no analysis. At paragraph 149 of his report, Dr. Wereley merely says: “I see no reason why the fact that certain of the modules have LEDs or displays integrated into their panel members takes them outside the scope of the claim language. For one, as discussed, the fact that these are non-fluidics components is not relevant since under the Court’s claim construction, only the fluidics section cannot have non-fluidics components such as electronics, and the panel member is a different section in that it is neither a ‘fluidics section’ nor a ‘non-fluidics section’.”

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79. Dr. Wereley makes the statement that he does not see any reason why the electronics “integrated into the panel members takes them outside the scope of the claim language without analyzing the file history to see how the inventors characterized their invention and how they treated what is a fluidics section. When the file history is examined, one of ordinary skill in the art can only come to the conclusion that what Dr. Wereley points to as a panel member and a fluidics section of the accused modules do not satisfy the requirements of the claims and are not consistent with how the inventors characterized their invention or the fluidics section in the file history. As a result, Dr. Wereley’s opening report fails to meet Plaintiffs’ burden of establishing the existence of this element in the accused modules.

80. Dr. Wereley merely concludes with absolutely no analysis that anything “integrated into the panel member” is a different section from the fluidics and electronics sections. I do not agree and neither would one of ordinary skill in the art who read the specification and the file history.

81. First, the inventors addressed this very issue in the file history. With respect to fluidics and electronics and the existence of separate sections, the inventors stated that the fluidics and the electronics need to be on either side of a panel. *See* Ex. G GEHC 001451 (The detector module 10 of Figure 10 illustrates that the fluid and electrical parts are adjacent, **not on either side of a panel**) (emphasis added); (“Bergstrom has given no thought to what happens when one unplugs a module and gets the electrical contacts 19 wet which will be inevitable since the contacts 19 appear to be housed in the cup shaped aperture 14... These problems in the Bergstrom design are not addressed in Burger, but are cleverly addressed in presently claimed invention **by separating the fluidic and non-fluidic parts of fluid handling units across a**

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**fluid handling panel and across a panel member of the modular components**, which inhibits the problems mentioned immediately above.”)(emphasis added)

82. The first quote from the inventors in the above paragraph shows that they consider the panel member, which like all physical objects has a thickness, has two sides, (*i.e.* “either sided”). It is apparent Dr. Wereley did not consider this fact. If he did, Dr. Wereley could not make the accused panel member consistent with the inventor statements by claiming that rather than two sides, the panel member has four sides: 1) the side the user sees, 2) the inner side of that side in the thickness of the panel, 3) the side that is mounted against the housing, 4) the inner side of that side which is also in the thickness of the panel. In standard English usage, which does not differ from the way one of ordinary skill in the art would understand what the inventors said, “either” indicates two options.

83. The same conclusion would be reached by one of skill in the art reading the second quote from Ex. G at page GEHC 1451 that I quoted above that the inventors made regarding the arrangement of the fluidics and electronics of a module. In the second quote, again distinguishing Bergstrom, the inventors stated that the fluidics must sit “**across**” two different panels: 1) the fluid handling panel and 2) the panel member. The accused products satisfy neither of these requirements and would not be considered by one of ordinary skill in the art to therefore contain a fluidics section with no electronics in the section.

84. As with the word “**either**” in the first quote, one of ordinary skill in the art would understand the use of the word “**across**” with reference to the fluidics and electronics of a panel being across two different panels to refer to the panel having two sides and the electronics and fluidics of a module lying on the opposite sides. That is not the case with the accused modules

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85. According to Dr. Wereley, the electronics are “embedded” in the panel member and thus part of a separate section from the fluidics. In addition to the fact that this embedded notion is inconsistent with the two statements I quoted above stating that the fluidics and electronics should be on either side of the panel member and across two different panels, the liquid handling panel, which the electronics and fluidics in the accused modules surely are not, and the panel member which they also are not – it is also inconsistent with other statements and the physical arrangements of the components in the Bergstrom reference that the inventors distinguished.

86. In the file history, the inventors stated that one can see how Bergstrom arranged his components in Figs. 1 and 4(a) where you can see a flow line 5 in baseplate 1. Ex. G at GEHC 1449. I reproduce those figures and others from Bergstrom (Ex. 21) below.



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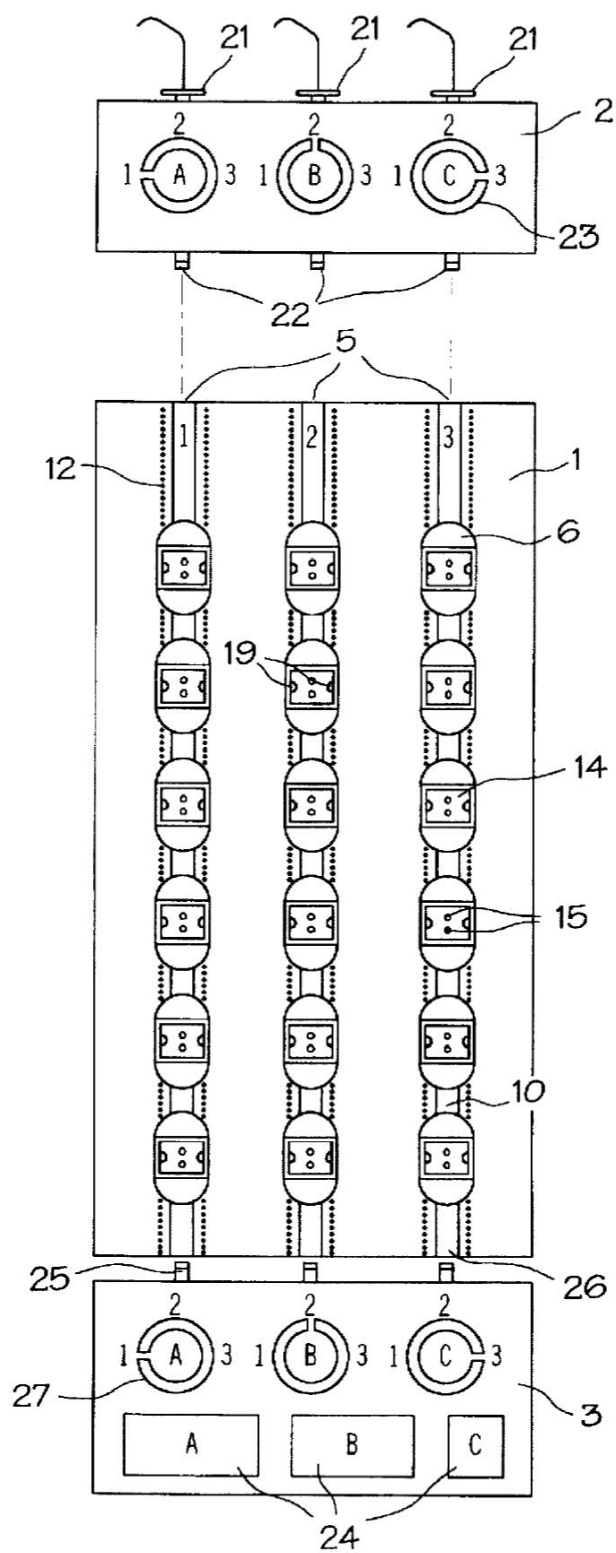


FIG. 1

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88. The inventors repeatedly described the flow line “5” as being adjacent to the electrical connectors “12” and therefore, having fluidics which are not separated from the electronics in the base plate “1” which had been equated to the panel member. Ex. G, GEHC at 1449-1451.

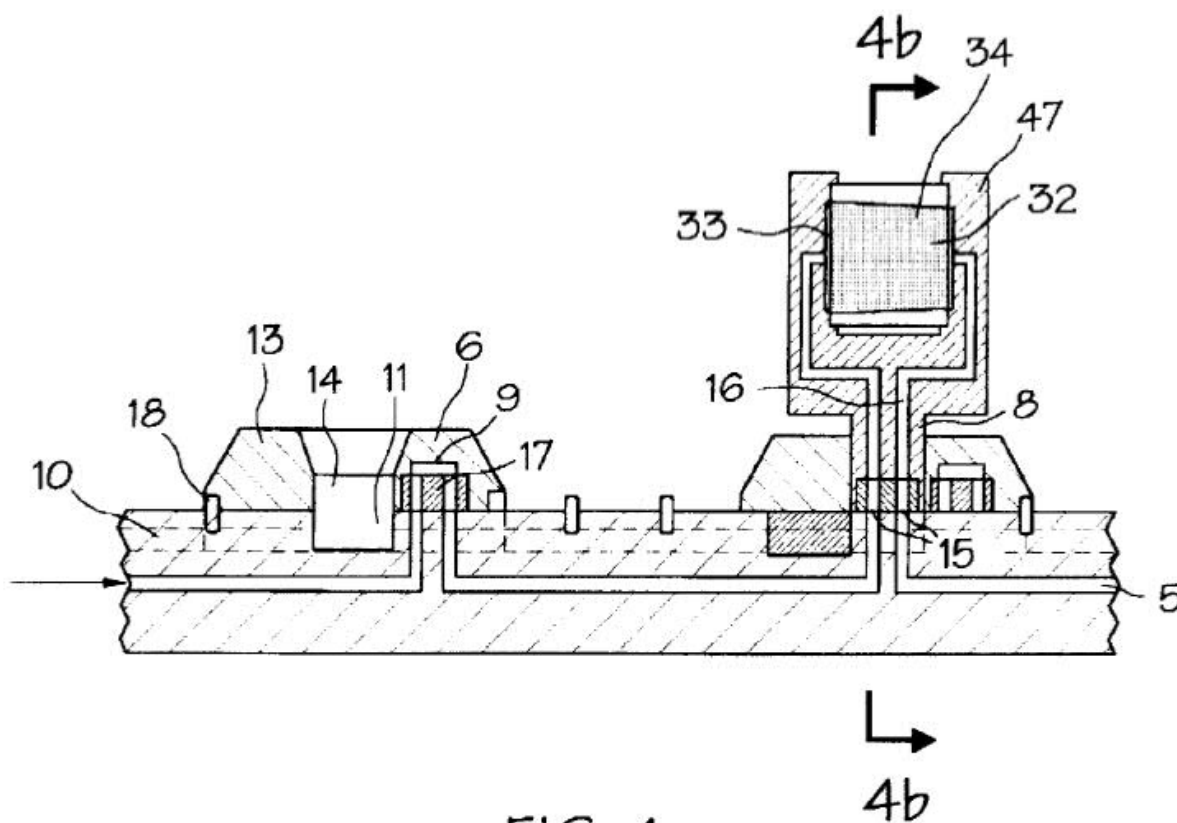
89. Dr. Wereley’s claim that electronics integrated in the thickness of the panel member are in a separate section and separated from the fluidics section of the module is inconsistent with what the inventors said about Bergstrom. As can be seen in Figure 4(a), which I reproduce below and which the inventors referenced when distinguishing Bergstrom as not having separate fluidics and electronics sections that were separated, the electronics lines “12” in Bergstrom are integrated in the base plate/panel member and are distanced from the fluid lines “5” which are also embedded in the base plate.

90. In Fig. 4(a) one sees a blow up of a single module “10” in base plate “1”. One can see in the figure that the flow line “5” is within the thickness of the base plate

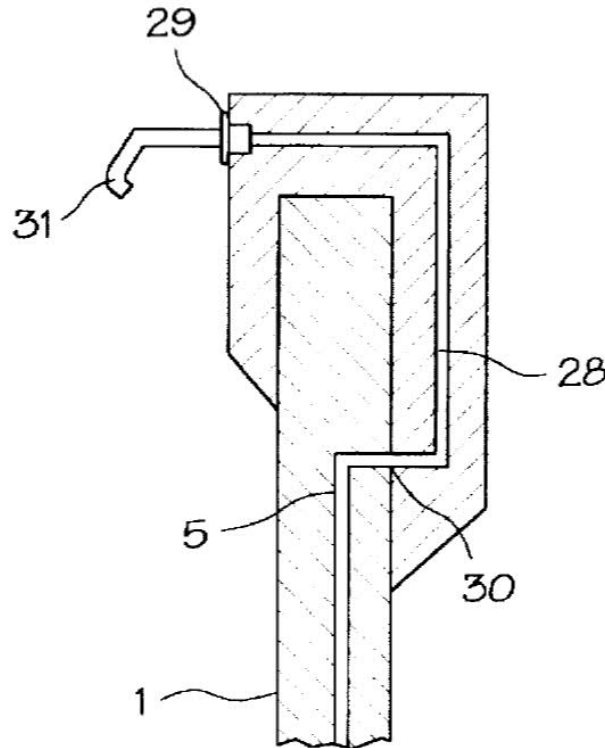
91. This is also shown in Fig. 2 which I also reproduce below.

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92. as



**HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS’ EYES ONLY**



**FIG. 2**

93.

94. Similarly, the Bergstrom specification states that the electrical lines “12” which are depicted in Fig. 1, are also embedded in baseplate 1. *See* Ex. 21 Bergstrom 5,766,460 at Col. 3:50-54 (One or more lines/conductors (12) for signal and power transmissions from or to connected modules may be arranged in the base plate (1) preferably along the flow lines (5).”. Nonetheless, even though the electronics were integrated in the thickness of the baseplate/panel member and so too were the fluid lines (5). Although those lines were parallel or near each other, they would have to be embedded in different thickness of the baseplate/panel member. But, consistent with the prior statements of the inventors that the fluids and electronics in a module had to be on different sides of two different panels, the inventors did not consider Bergstrom to have modules with separate fluid and electronics sections or have those sections separated.

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95. Consequently, Dr. Wereley’s analysis that having electronics integrated in the thickness of the panel member creates a different section that is separated from the fluidics section, is not consistent with the file history and one of ordinary skill would not come to the same conclusion that Dr. Wereley did. Rather, after reading the portions of the file history I have discussed thus far, one of ordinary skill in the art would conclude that the accused modules do not have an external fluidics section—one that has no electrical components.

96. Dr. Wereley’s analysis that integrated electronics are a separate section from the fluidics does not consider at all that such an analysis fails to account for the accused devices and the analysis regarding them being inconsistent with the purpose of the invention. As I detailed previously, the patent, the inventor and plaintiff’s prior experts also stressed that the purpose of the invention was to have electronics and fluidics in distinct sections that are separated and sealed from each other so as to keep the fluids from wetting or damaging the electronics such as when fluid connections are being changed or if there is a leak. That is not the case in the accused devices.

97. As I explained above and as can be seen in the photo of the assembly procedure for the inject valve that I reproduced in this report, the overlay attaches to the face plate only with a few drops of glue. That method of attachment is not sufficient to seal the electronics which Dr. Wereley says are “integrated” in the “panel member” from fluids on the module. To confirm this, I physically examined at least two different modules recently, a pump module and a pH module with respect to the relationship between the overlay and the faceplate. I confirmed by looking at these physical samples that fluid that leaks from the modules would not be sealed from the electronics Dr. Wereley describes as being integrated in the panel member.

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98. To be sure of this, I also spoke to Bio-Rad employee Joe Hilario. I understand that Mr. Hilario has experience with and responsibility for assembly of Bio-Rad modules and is familiar through his experience with whether fluid can seep into and wet the electronics that Dr. Wereley states are integrated in the panel member. Mr. Hilario confirmed, consistent with my examination of the modules, that in fact leaking fluid can wet the electronics that Dr. Wereley describes as being embedded in the panel member. My examination and Mr. Hilario confirmed that there is no sealing member, like a gasket, that seals the overlay to the faceplate and prevents electronics from getting wet. Consistent with this fact, The Bio-Rad products do not carry the same classification specified by a certifying organization as the Cytiva products, with respect to the degree that electronics and fluidics are separated from each other.

99. Consequently, the actual facts related to the accused modules demonstrate that they are not consistent with the purpose of the invention, to separate the fluids in a module from the electronics and therefore, have them in separate sections where the likelihood of the electronics getting wet is low. This fact also demonstrates that Dr. Wereley’s conclusion that electronics “embedded in the panel member” as Dr. Wereley describes them, are not in a different section from the fluidics. For one of ordinary skill in the art to determine that fluids and electronics are in separate sections, they should be arranged and separated in such a way that the purpose of the invention will be fulfilled—electronics will not get wet if there is a fluid leak.

100. Yet another set of representations in the file history from the inventors that are inconsistent with Dr. Wereley’s summary conclusion that electronics integrated in the panel

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member<sup>4</sup> of the accused modules are in a separate section from the fluidics are the representations about the Hess reference.

101. The applicants distinguished the Hess reference as not having a fluidics section separated from a non fluidics section because the modules in Hess had an electrical connection coming out of the back of a module while there were fluids on the front of the module. *See* Ex. G at 1416-1417 (“Therefore, the boxes of Hess must be electrically interconnected, and it follows that these connections are external to said boxes and not internal to any housing... This means that the bus connections cannot be internal to said boxes or internal to any ‘housing.’ On the contrary, the bus connections must be external to said boxes to make sense of the description. Therefore, in Hess, respective non fluidics sections are not internal to any housing as claimed.”).

102. The inventors recognized that Hess had an internal electronics sections that was separated and sealed from the fluidics section: *See* Ex. G at 1423 (“Since the Hess design was conceived with radioactive product processing in mind [e.g. see abstract] the need for sealing each box and electrically connecting each box such that liquid radioactive contamination does not penetrate the boxes or box electrical interconnections is very important, but results in a costly system.”).

103. Nonetheless, the inventors stated that Hess was inconsistent with the invention because although it had electronics inside a housing that was separated and sealed from fluidics, there was one electrical component, a bus interconnection that was external and not internal to said housing in Hess. *See, e.g.,* Ex. G at 1424 (“Therefore, the boxes of Hess must be

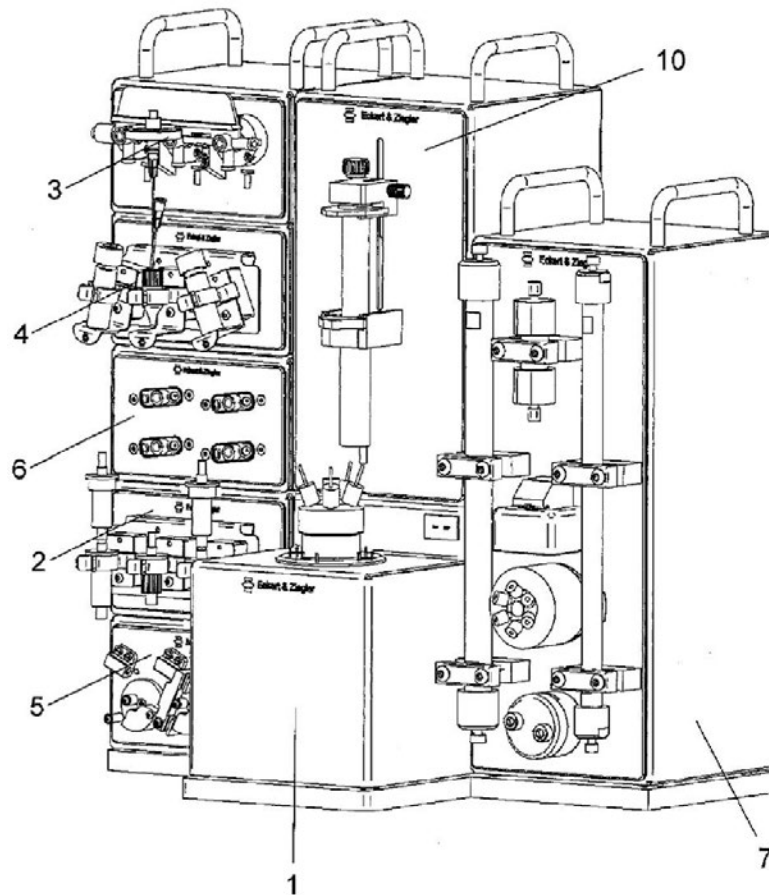
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<sup>4</sup> I am simply repeating Dr. Wereley’s description of the arrangement but not agreeing with it.

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electrically interconnected, and it follows that these connections are external to said boxes and not internal to any ‘housing’.”). According to the inventors, the electrical connections had to be at the back of the boxes. *Id.* at 1416 (“So by process of elimination, bus connections [in Hess] have to be at the back of the boxes – there is no other place for them if the boxes are stackable and fit side by side as illustrated.”).

104. Below, I have reproduced an exemplary figure from the Hess reference (Ex. 22). In Fig. 2 below one of ordinary skill in the art can see that the system has fluid components on the front of the boxes, while the bus connections that the inventors described are on the opposite side and cannot be seen.



**Fig. 2**

105.



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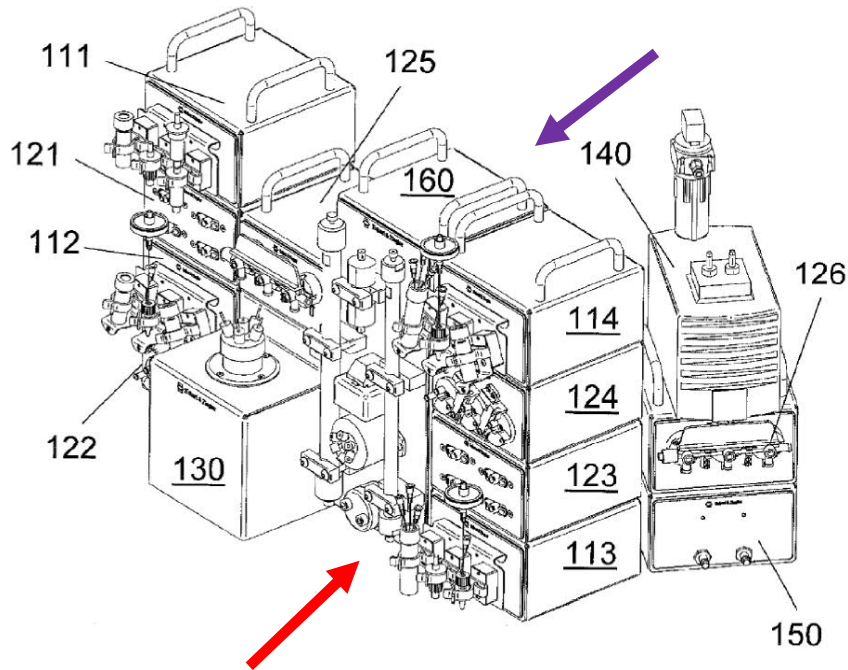


Fig. 4

106.

107. In this arrangement, one of ordinary skill in the art would see the bus connections at the back of the boxes, purple arrow, would be on the other side of at least two walls from the fluidics, which are indicated with a red arrow. Even with this two wall separation, the inventors said the arrangement was inconsistent with their invention. There is no way to square this representation about Hess, with Dr. Wereley's claim that electronics integrated in the panel member are in a separate section from the fluidics in the accused modules. The electronics in Hess are on the other side of two walls from the fluidics, not right next to them as in the accused modules, yet the inventors said this was not separation and not its invention because there was a single electrical component that was not inside the housing even though there were many other electrical components inside the housing.

108. The inventors further stressed why this type of arrangement was not its invention. Not only did the inventors consider that their invention had to have the fluidic and electronic

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components of a module separated, such that there were distinct and separate fluidics and electronics sections in the module, but the separation had to be accomplished in a particular way which is inconsistent with Dr. Wereley’s analysis.

109. Even if one of ordinary skill in the art would assume, contrary to the facts, that electronics integrated in the panel member of the accused products somehow separated them from the fluidics in the modules and protected them from getting wet, this is not consistent with the invention as the inventors represented it to the Examiner. The inventors unequivocally stated, over and over again, that any protection of electronics of a module had to consist of “collective” protection in which one module’s electronics were being protected in the same way and in the same structure as all the other modules’ electronics.

110. The inventors described the collective protection of the electronics of a module of the invention as follows in distinguishing it from Hess in Ex. G at 1414-1415:

According to the claimed invention, the liquid handling panel of the housing, together with the panel members of the modular components is arranged to separate the fluidics sections with respect to the non fluidics sections of the modular components such that the respective fluidics sections are external to the housing and the respective non

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111.

GEHC 001414

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Amendment dated May 28, 2014  
Reply to Office action of March 17, 2014

fluidics sections are internal to the housing. In general terms, as pointed out in the present application [0060], this concept allows for collective liquid protection of internal parts of the modular components present inside the housing and separated from the fluidics sections by the fluid handling panel/members. In contrast, in the design of Hess, each independent module needs to be sealed and resistant to liquids in order to provide a safe working environment and to comply with relevant regulations for fluid handling systems.

Since the Hess design was conceived with radioactive product processing in mind [e.g. see abstract] the need for sealing each box and electrically connecting each box such that liquid radioactive contamination does not penetrate the boxes or electrical interconnections is very important, but results in a costly system. The presently claimed system provides a much lower cost alternative to the Hess design because the collective protection of the housing claimed negates the need for the individual sealed boxes of Hess.

Applicant submits also that there is no disclosure in Hess of the separation concept of the fluidic sections and the non fluidic sections as claimed in present claim 1 “such that said respective fluidics sections are external to the housing and said respective non fluidics sections are internal to the housing”. In Hess, each individual box must be connected to the bus in some way, but nothing detailed is illustrated concerning any connection. In this regard, the most pertinent description in Hess appears to be [0077] and [0078]:

*[0077] To further reduce the complexity of the configuration, the system may include an intelligent bus system which recognizes connected components. Advantageously, standard connecting cables can be employed which only differ by having different lengths.*

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113. At best, (which I do not agree with) what Dr. Wereley describes as electronics integrated in the panel member to create a section distinct from the fluidics section would be an example of individual protection of fluidics from electronics in each module that the inventors distinguished their invention from over Hess. Such individual protection does not provide the “collective protection” that the inventors said was necessary in their invention. In other words, the electronics integrated in each panel member of each module in the Bio-Rad accused modules and system are not protected from the fluidics by being inside a housing that protects them all. Rather the integrated electronics that Dr. Wereley points to are each protected individually.

114. A person of ordinary skill in the art reading the inventors’ statements about Hess would recognize that if in Hess, a single electronic cable exiting the back of a module, in which the cable was spaced apart from the fluidics at the front of the module by at least two walls and a much greater distance than the electronics in the Bio-Rad accused devices are distanced from the fluidics, did not constitute a distinct section that was separated from the fluidics section, then neither does what Dr. Wereley calls the electronics integrated in the panel member of the accused modules.

115. For these reasons, the accused devices do not have an external fluidics section. Similarly, the subsequent elements that I will discuss in the following paragraphs relating to the non fluidics section and the separation of the fluidics from the non fluidics by a panel member and the non fluidics section being internal to the housing and separated from the fluidics by a liquid handling panel when the module is inserted into the housing are also not met.

**2. Element [1.f]: “an internal non-fluidics section”**

116. Element [1.f] of the ’420 patent requires “an internal non-fluidics section.”

117. The NGC System does not infringe this element because the NGC System does not include “an internal non-fluidics section” as required by claim 1 of the ’420 patent. As

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detailed with respect to element 1(e) in the prior paragraphs, which I incorporated herein, each of the Bio-Rad accused modules contain either LED lights, a display or both that are visible to the user and on the same side of the panel member as the fluidics. The pump modules also have electronic switches on the same side of the panel member as the fluidics. They also contain electronics such as a PCB and ribbon line in the “overlay” shown in the assembly documents cited and that are exhibits to this report. These are all part of the non-fluidics section and cannot simply be considered a separate section from the electronics that are inside the housing.

118. In paragraphs 118- 126 Dr. Wereley concludes that there is a non fluidic section, one that he believes does not have fluidics, by pointing to electronics inside the housing. But, as discussed previously, Dr. Wereley does not at all consider the File History. As I discussed previously regarding element 1(e), when the file history is examined, one of ordinary skill in the art can only come to the conclusion that there is not a non fluidics section in the accused Bio-Rad modules.

119. For example, the Hess reference certainly had electronics that were sealed in a box and separated from the fluidics that were outside the housing and on the front face visible to the user. *See* Ex. G at 1423 (“Since the Hess design was conceived with radioactive product processing in mind [e.g. see abstract] the need for sealing each box and electrically connecting each box such that liquid radioactive contamination does not penetrate the boxes or box electrical interconnections is very important, but results in a costly system.”); *See* Figs. 2 and 4 reproduced above from the Hess reference showing the fluidics.

120. Nonetheless, as shown in the previous element, the inventors stated Hess was distinct from their invention because there was a single electrical component, a connector between modules, that exited from the back of each module. The inventors considered that

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single electrical line to be part of the non fluidics section of each module and not separated from the fluidics of each module.

121. There is no way to distinguish the arrangement of Hess and the arguments the inventors made regarding there being electrical components not separated from fluidic components in the Hess modules from the arrangement in the Bio-Rad accused modules. Each of the Bio-Rad modules has electronics that are not inside the housing, just like Hess. Therefore the Bio-Rad modules do not have a non fluidics section.

122. Further as discussed with element 1(e), it is not proper to call the electronics in the accused devices that are “integrated in the panel member” a section that is distinct from either the electronics inside the housing or the fluidics outside the housing. For example, as discussed previously, with respect to the figures of Bergstrom that I reproduced above showing the flow channel 5 and the electrical lines 12, the Bergstrom reference has electronics and fluidics integrated in a baseplate structure, yet the inventors did not consider them to be distinct sections that were separated. Moreover, the inventors stated that for electronics and fluidics to be in separate sections, they had to be on opposite sides of a at least two different panels—the panel member and the liquid handling panel. Ex. G at 1451. There is no way for this to be true and the Bio-Rad accused modules to meet the claim limitation.

123. As I discussed previously, I do not believe the overlay is the panel member. Thus, the electronics that Dr. Wereley states are “integrated in the panel member are actually in the overlay and on the same side of the panel member (faceplate) as the fluidics. Moreover, even if one considers the overlay and the faceplate as being a single unit that is the panel member, the fluidics and electronics are still not on opposite sides of the two required panel members—the liquid handling panel and the panel member as the inventors stated they must be. Ex. G at 1451.

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124. For all these reasons and those discussed with respect to element 1(e), the three accused Bio-Rad liquid handling units do not have a non fluidics section.

**3. Element [1.h]: “a panel member arranged to separate the fluidics section from the non-fluidics section”**

125. Element [1.h] of the ’420 patent requires “a panel member arranged to separate the fluidics section from the non-fluidics section.”

126. The NGC System does not infringe this element because the NGC System does not include “a panel member arranged to separate the fluidics section from the non-fluidics section” as claimed. I incorporate my discussion of the prior two elements for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as integrated in the panel member. “Integrating” as shown with the arrangement of Bergstrom, does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being integrated in the panel member are the fluidics in the Bio-Rad accused modules, which are not on “either side” of the panel member as the inventors said they must be. Ex. G at 1451 (“The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel.**”)(emphasis added).

**4. Element [1.i]: “wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing.”**

127. Element [1.i] of the ’420 patent requires “wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional



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array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing.”

128. I have discussed why this element is not met with respect to my discussion of elements 1(e), 1(f) and 1(h). I incorporate those discussions fully for this element.

129. The NGC System does not infringe this element because the alleged housing lacks the underlined portions of the claim element: “a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing.”

130. In summary, the failure of proof for this element is most easily demonstrated with reference to the inventors’ discussion of the Hess reference. As discussed with respect to elements 1(e) and 1(f), in the Hess reference, each module had electronics sealed in a box and fluidics visible from a side that one can consider the front of the box. The inventors pointed out that what the examiner was considering the modules also had a single electrical connection exiting the back of the box. *See e.g.*, ¶¶ 107-112 herein. For this reason, they concluded that Hess did not have a non fluidics section internal to said housing and a fluidics section external to said housing. There is no way for one of ordinary skill in the art to distinguish the arrangement in Hess that the inventors said was outside the scope of their invention with the arrangement in the accused modules. In the accused modules, there are electronics outside the housing. Those electronics cannot be a section that is distinct from the electronics that are inside the housing, just like the single electronic connection in Hess was not distinct from the electronics contained in the sealed boxes. Because the electronics inside the sealed boxes in Hess, that the examiner



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considered a housing did not constitute a non fluidics section that was internal to said housing when inserted, one of ordinary skill in the art could not also consider the electronics that Dr. Wereley considered to be embedded in the panel member to be a non fluidic section that is distinct from the electronics that are inside the housing in the Bio-Rad accused modules.

131. Therefore, Dr. Wereley has failed to meet his burden to establish the existence of this element in the accused fluid handling modules.

**5. Element [1.k]: “wherein each interchangeable modular component includes a dedicated cpu unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus”**

132. Element [1.k] of the ’420 patent requires “wherein each interchangeable modular component includes a dedicated cpu unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus.”

133. The NGC System does not infringe any claims of the ’420 patent because the alleged interchangeable modular component lacks “a dedicated cpu unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus” as claimed.

134. In particular, Dr. Wereley, at paragraphs 160-170 of his report where he discusses this element, has not established and met his burden of proof that each module acts independently to perform operations after receiving instructions over the bus. First, I do not believe that Dr. Wereley has used the proper definition of the CPU’s on the modules acting independently. Second, I do not see proof under the definition that he does use that each of the accused modules acts independently of other modules.

135. Dr. Wereley interprets the “independent” language in the claim to mean independent of other modules. *See* Wereley ¶167. But that is not how one of ordinary skill in

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the art would interpret that limitation. The specification gives two alternatives for control. First it describes the master control unit communicating with each module over a bus and those control signals issued by the MCU controlling the modules. *See* Col. 7: 57-60 (“As mentioned above, the chromatography system may comprise a master control unit 40 arranged to communicate with all modular components e.g. 1-26 over a system bus 42 such as a CAN-bus or the like”). In that embodiment, something other than a CPU on the module would instruct the module what to do. The control function could be carried out by for example a particular voltage/current that would make a pump operate at a certain rate. (e.g., A high signal makes the motor operate at one rate and a low signal makes it operate at another rate).

136. Alternatively, the specification indicates that each module could also have a CPU that would allow the module to independently perform operations in response to instructions over the bus. *See* col. 7: 60-63 (“In one embodiment, each modular component is provided with a dedicated CPU unit allowing the component to independently perform operations in response to instructions over the BUS 42.”) One of ordinary skill in the art would not read that alternative to do nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (e.g., A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely forward it to another device to create that same current or voltage or simply translate that instruction into a different format.

137. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the **independent** operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that

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signal indicates and what the MCU would have done on its own, something that is independent of the signal the MPU sent.

138. One example of that would be the function described for the 2040 instrument which I detailed in my invalidity report. In the 2040, the burette modules have a CPU located directly on them. The 2040 User Manual indicates that the burette modules have very precise control – the ability to vary flow in one of 10,000 increments. To maintain such precise control, one of ordinary skill in the art would recognize that the burette module, using its CPU is independently monitoring the flow value and constantly making adjustments to ensure the set value is being maintained. In that situation, the CPU on the burette is operating independently of the master control unit which would have only sent the original instruction for what the initial parameter should be.

139. Given that the specification describes the back to back situations where either: 1) the Master Control Unit controls the operation of the module, and contrasts that with 2) the situation where the CPU independently controls an operation of the module in response to an instruction from the MCU, one of ordinary skill in the art would not understand the independent control to be control that is independent of what is occurring in other modules as Dr. Wereley does.

140. Contrary to what Dr. Wereley concludes at paragraph 167, the mention of the MCU and the fact that the MCU needs to send instructions would not lead one of ordinary skill in the art to interpret independently to mean independent of other modules just because the CPU must receive some signal from the MCU. [REDACTED]

[REDACTED]

[REDACTED]

As I explained in the

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paragraph above relating to what the 2040 burette module does, just because a CPU receives an instruction from an MCU does not mean that functions carried out by the CPU cannot be independent of the MCU command.

141. There is no reference in the specification to modules communicating with each other in relation to the control function. Rather the two embodiments in the specification that are directed to this limitation relate to the MCU controlling the module, or the CPU on the module receiving a signal from the MCU and then acting independently of the MCU in carrying out some function on the module.

142. I do not see anything in the testimony that Dr. Wereley cited that leads to a different conclusion. First, Dr. Wereley cites the testimony of Mr. Iovanni who testified that [REDACTED]  
[REDACTED] See Wereley ¶

168. [REDACTED]  
[REDACTED] It is fully  
consistent with the definition I have put forward. [REDACTED]

[REDACTED]  
[REDACTED] Moreover, as I explain below, one of ordinary  
skill in the art would not look to the Bio-Rad accused product to determine how to interpret the  
independent limitation in the patent, a limitation created by a different company related to a  
different system.

143. Mr. Bland’s testimony that Dr. Wereley cites also does not support his  
construction of this element of the claim. All that Mr. Bland testified was that in the accused  
system, [REDACTED]. *Id.* at ¶  
168, pages 108-109. But, that does not mean that is what the claim term in the patent means.

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That would be like saying that a car that can maintain its speed independent of a driver pressing the accelerator pedal, defines the meaning of a claim in a patent written about a different car that says the car operates independently of operator control. Independent of operator control could certainly relate to an autonomous driving system, not simply cruise control. One needs to see how the term is used in the patent, not some application outside the patent. There is no way to link those facts to determine the meaning of the claim element. I understand that the element of a patent claim must be interpreted in light of what is disclosed in the specification, not with reference to an accused device. If the latter was the method of interpretation, than one would always interpret the claim with the way the accused product worked and there would always be infringement of every patent.

144. Moreover, Mr. Bland’s testimony shows that the CPU’s on the accused modules do not act independently of the instructions from the MCU. As Dr. Wereley put in his report, Mr. Bland testified that: [REDACTED]

[REDACTED] *Id.* at ¶168 p. 108. This testimony indicates [REDACTED] not that it is operating independently.

145. I understand that Bio-Rad identified its understanding of the independent requirement in its non-infringement contentions. *See e.g.*, ROG Response 6 supplemented on May 22, 2020. By choosing not to address this construction at all in his opening report, I understand that neither Dr. Wereley nor Mr. Vukicevic can raise it either one of their responsive reports.

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146. Next, even if Dr. Wereley’s construction were correct, that independent means: “that the particular module’s operations be independent from the operations of other modules installed in the system.”

147. First, I have reviewed the report of Mr. Vukicevic who allegedly studied the source code to show that it operated in a way consistent with the claims. I do not find that what he states in his report establishes that. For example, nowhere in his report does Mr. Vukicevic state that the Master Control unit issues commands over a bus to a CPU on each of the accused modules that then uses those commands to control the operation of the module independently of other modules. The closest he comes is in paragraph 5, but that paragraph does not say that commands travel over a bus and control each of the accused modules independently of other modules

148. After identifying a number of file names, which I do not think prove anything about the existence of the disputed element, Mr. Vukicevic states that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Vukicevic at ¶ 5. But this proves nothing with respect to the element. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] He also says nothing about the claimed bus or any requirement for independence.

149. In paragraph 7 Mr. Vukicevic states that [REDACTED]

[REDACTED]

This does not indicate that the claim

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limitation is being used. It does not identify what is sending the signals, how they are being sent and to what on the CU.

150. So, nothing that I see in Mr. Vukicevic’s report establishes that the accused devices function in the manner claimed. In fact, in the next few sentences, Mr. Vukicevic states

[REDACTED]

[REDACTED] Again, this does not establish that the MCU is sending the commands, over a bus to the CPU on each module. Nor does it establish that each CPU is acting independently from the CPU on any other module as Dr. Wereley interprets the limitation. [REDACTED]

[REDACTED]

[REDACTED]

151. Dr. Wereley’s independent analysis of this element also does not establish the existence of this element in the accused device. Thus, Dr. Wereley has failed to meet his burden in his opening report.

152. In particular, nothing in paragraphs 160-170 of Dr. Wereley’s report establishes that the CPU on each of the accused modules is receiving signals over a system bus that then cause it to carry out operations on the module. Moreover, nothing in those paragraphs of Dr. Wereley’s report indicate that any signals that the CPUs receive are from the MCU which is the only description the specification contains for where the signals must be coming from. See Col. 7: 54-67, Description of Fig. 8 Dr. Wereley nowhere in his report identifies where the signals are originating from. Thus he has failed to meet his burden to establish this element. Additionally, see next element. Further, the separate computer that a user of the Bio-Rad accused devices uses to input information and which contains the user interface is not the MCU as described in the specification. Rather, it is a distinct control computer. See Col. 8: (“The master control unit 40

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comprises a system controller 46 for communicating with internal and external components and control computers (not shown)”). Indeed, having a master control unit outside the housing would also be inconsistent with how the inventors distinguished Hess during prosecution, as it would require a bus outside of the housing.

**6. Element [1.1]: “wherein the master control unit is arranged to automatically identify interchangeable modular components”**

153. Element [1.1] of the ’420 patent requires “wherein the master control unit is arranged to automatically identify interchangeable modular components.”

154. The NGC System does not infringe any claims of the ’420 patent because the alleged master control unit is not “arranged to automatically identify interchangeable modular components” as claimed. The evidence that Dr. Wereley cites at paragraphs 171-174 shows that this element is not met. Rather than showing that the MCU automatically identifies an interchangeable modular unit, the testimony of Mr. Bland that Dr. Wereley cited shows that [REDACTED] [REDACTED] See e.g., Wereley at ¶ 171.

155. The NGC Instrument guide also does not establish that the MCU identifies each interchangeable module that inserted into the machine. All the guide says is: “Each module has a unique electronic ID that enables the system to recognize its function when the module is placed into the bay. For example, the system can distinguish between a sample inject valve module and a sample inlet valve module even though they each occupy a single wide slot.” See Wereley at ¶171. [REDACTED]

[REDACTED]. *Id.*



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156. But the fact that the system identifies a module does not mean the element is met. The system is composed of multiple elements. The claim element, however, is very specific. The MCU is the component in the system that must identify the module inserted into the housing. The fact that the identity may be passed on to the MCU at some point after it is identified by some other component of the system does not satisfy the element. One of ordinary skill in the art would understand identify to mean the component that makes the identification, not any component that later receives the information. This is consistent with the specification which states it is the MCU which makes the identification and not CPU’s on modules. Col. 8: 8-14 (“According to one embodiment, different component modules are automatically identified by the master control unit, whereby they may be moved essentially freely between different positions. Moreover, the master control unit may be arranged to provide said information to Chromatography control software whereby experimental setup and planning may be performed.”). This passage makes clear to one of ordinary skill in the art that having one device in a system identifying a module is different from that device passing that identity on to other devices in the system as occurs in the accused system.

157. Last, I see nothing in Mr. Vukicevic’s report that shows that Plaintiff has met its burden of establishing the existence of this element. In paragraph 8 of his report, Mr. Vukicevic states that [REDACTED] Vukicevic, ¶ 8. First, Mr. Vukicevic is not even sure if this is the case. Second, nothing in this sentence or in any other part of Mr. Vukicevic’s report establish that it is the MCU, which identifies the modules as the claim requires.

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158. Therefore, Dr. Wereley, Mr. Vukicevic and Plaintiffs have failed to establish the existence of this element in the accused devices. .

7. **Element [1.m]: “wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least three of the pump, the sensor unit and the fluid control valves are interchangeable modular components”**

159. For the reasons stated previously the sample inject module and the two system pump modules are not interchangeable modular components because the interchangeable modular components of claim 1 need to have the fluidics and non fluidics sections of elements 1.e and 1.f as well as the separation requirements of elements 1 (h, i, j) and the independent operations requirements of element 1.k and identification requirement of 1(l) which the sample inject module and the two pump modules do not have as described previously which I incorporate herein. The same is true for the other fluid handling modules that Dr. Wereley identifies as alternatives to the pump and inject valve for this element.

160. Further, with respect to the UV module that Dr. Wereley relies on to satisfy this claim element, he identifies a sensor unit, but neither the Bio-Rad single or multi-wavelength UV detectors qualifies as interchangeable modular units that can satisfy this element because neither has the required fluidics and non fluidics sections, a panel member for separating those sections, and a liquid handling panel for separating those sections, nor does either satisfy the requirement that the electronics be internal to the housing when inserted.

161. One of ordinary skill in the art reading the file history, specification and claims would conclude that the Bio-Rad single and multi-wavelength detectors are not interchangeable modular units as required by the claims. In fact, the inventors addressed this very type of component and unequivocally stated that such a detector did not come within the claims of its invention.

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162. In distinguishing the Bergstrom reference the inventors pointed to the detector module 10 as not being within the realm of its invention. *See* Ex. G at GEHC 1450. In particular, the inventors first said:

lines/conductors 12 [column 3 lines 50-58]. Further, column 7 lines 3 to 11 describes signal communication to a detector module 40 (Figure 10) via contacts 20 on the module and corresponding contacts 19 (Figure 1) on the base plate 1. The detector 40 also includes a processing unit 55, which is very likely to be electronic in nature and conductors 41 which both appear to be next to liquid paths. It is suggested that other modules will have corresponding power and signal paths: “other modules (for instance valve modules) may be provided with power and signal transmission lines/conductors.” [column 7 lines 8-10].

163.

164. The Bergstrom specification at Col. 7: 3-11 describes that the detector module can be based on pH, UV, IR, conductivity, capacitance refractive index, etc.:

**7**

**function in the form of valves, filter, matrices, additional connection, detectors, etc.**

**FIG. 10 illustrates a detector module. The detector unit (40) may be based on pH, UV, IR, conductivity, capacitance, refractive index, etc. The transmission of signals from the module is effected through lines/conductors (41) and contacts (20) to corresponding contacts (19—shown in FIG. 1) in the connecting device. Correspondingly, other modules (for instance valve modules) may be provided with power and signal transmission lines/conductors. Detector modules may be equipped with signal processing units (55).**

165.

166. The Bio-Rad UV modules have both a UV detector and a conductivity detector on them as can be seen in the images below along with Fig. 10 from the Bergstrom patent:

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167.



168.

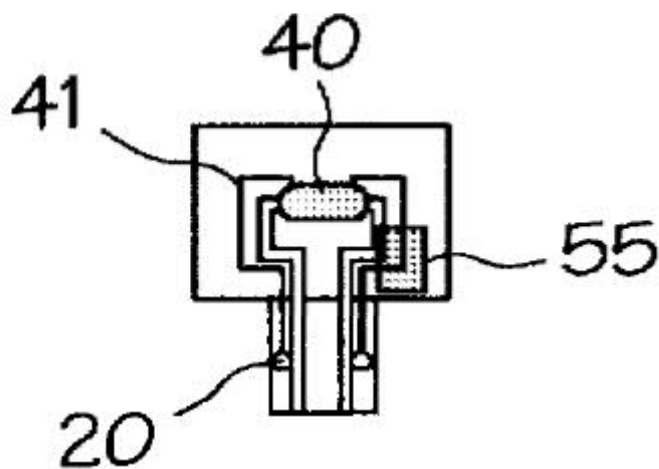


FIG. 10

169.

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170. Further images of the Bio-Rad UV and conductivity detectors are attached as an exhibit to this report.

171. The inventors made it clear and unequivocally stated that a detector, such as a single or multiwavelength detector which Dr. Wereley has accused of satisfying this element cannot.

172. The statements were so clear that even Cytiva's prior expert Dr. Scandella recognized that the UV detector had electronics on the same side of the panel member as the fluidics section. That testimony is reproduced below:

11 BY MR. BILSKER:

12 Q So let's see if you can answer it again.

13 Is the screen on the Bio-Rad Multi UV Wavelength  
14 Detector, is that electronics?

15 A As an isolated element, it is electronics, 10:18:49  
16 yes.

17 Q Is it an electrical component?

18 A It is an electrical component, yes.

19 Q And that electrical component, is that  
20 internal or external to the housing of the machine? 10:19:08

21 A Well, I, as not an expert in this area,  
22 assume that the surface of the screen is -- is not  
23 an electrical component. What's behind it is an  
24 electrical component.

25 Q Do you know whether any of the electrical 10:19:22  
Page 37

173. \_\_\_\_\_



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15 Q Really? So you think the claim is -- you 10:26:32  
16 think it's fine to have electronics and electrical  
17 components external to the housing of the machine?

18 A For example, the conductivity cell that  
19 you've already pointed to is external to the  
20 machine. 10:26:46

21 Q I know that.

22 A And if you consider that the -- that the  
23 electrodes of the conductivity cell are electronics  
24 or electronic, or whatever you want to -- however  
25 you want to define that, then that's external to the 10:26:58

Page 44

1 machine, yes.

2 Q And the light source is an electrical  
3 component, and that would be external to the housing  
4 of the machine, correct?

5 A It might be. I didn't determine where the 10:27:08  
6 light source was.

7 Q Well, let's assume that the light source is  
8 contained within -- within that housing that you  
9 point to that says fluidics section. Do you see  
10 that? 10:27:28

11 A Okay.

12 Q If it's contained within that, that would  
13 be an electrical component which is external to the  
14 housing of the machine, correct?

15 MR. NISHIMOTO: Objection. Form. 10:27:37

174. 16 THE WITNESS: Yes, I think so.

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175. In fact, Dr. Scandella testified at p. 48 of his deposition that the UV module, which was exhibit 41 to his report contained electronic components on the same side of the panel member as the fluidics.

12 Q The module shown in Figure 41 --

13 A Yes.

14 Q -- in your declaration has electrical

15 components on the same side of the panel as the 10:30:5

16 fluidics section, correct?

17 A Right.

176.

177. I reproduce Fig. 41 along with Dr. Scandella’s annotations of the figure and a short paragraph from his report describing the figure below:

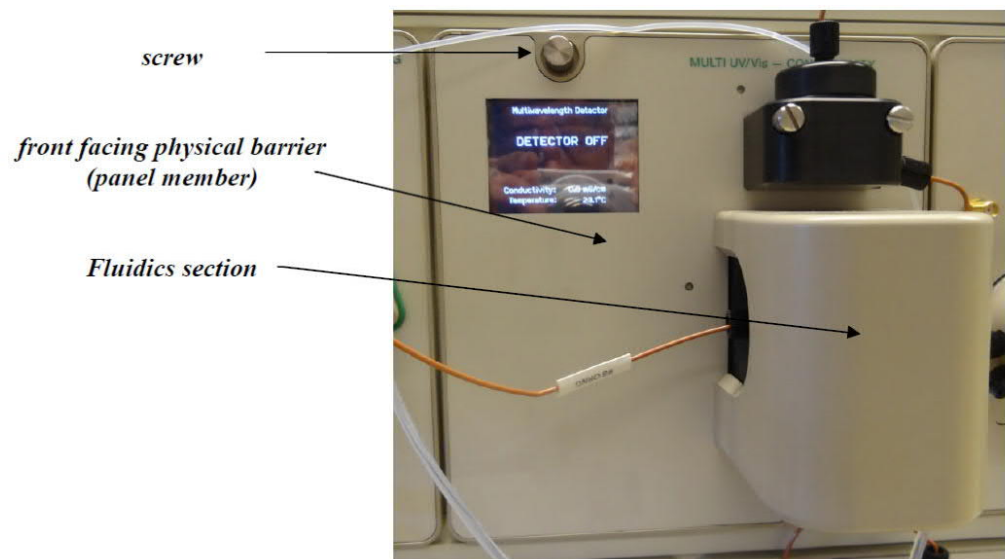


Fig. 41

42. The panel member also provides for attachment of the modular component to the liquid handling panel. Specifically, the panel member contains a screw or screws (shown in Figure 41 above) which, when tightened, attach the modular component to the liquid handling panel (shown in Figure 42 below). *See also* NGC Instrument Guide v. 1 pp. 187-188

178.

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179. Given the statements of the inventors, the testimony of Dr. Scandella and the images of the UV and conductivity detector, one of ordinary skill in the art could not conclude that the UV/Conductivity modules have: fluidics and non fluidics sections, that they have a panel member that separates the fluidic from non fluidic sections, that they have a liquid handling panel that separates fluid from non fluidics, that the non fluidic electronic section is internal to the housing when inserted into the respective cavity of the housing. I have confirmed in conversations with Joe Hilario that each of the Bio-Rad UV/Conductivity modules (eg single and multi-wavelength) have electronics outside the housing and on the same side of the panel member as the fluidics section. For example, [REDACTED]

[REDACTED]. . For at least all these reasons, the UV/Conductivity module cannot meet this claim element. I did not see any other sensor unit that Dr. Wereley relied on to meet the sensor limitation, but even if he did, all the sensor units that Bio-Rad can use in the accused systems contain the same arrangement as the UV/Conductivity modules. There are electronics that are part of the modules that are on the outside of the housing and on the same side of the panel member as the fluidics. Thus, such sensor units would not meet the limitations of the claims for the reasons already described previously for the liquid handling units. Moreover sensor units such as the PH detector contain additional electronics that are part of the module, external rather than internal to the housing and on the same side of the panel member as the fluidics. The PH detector has an electrode that is placed in contact with fluid and is part of the module. Thus the PH detector module cannot meet this limitation of claim 1 or the limitations of claim 5 below.



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180. Many of the subsequent claims contain the same limitations and whether or not specifically stated, the arguments made thus far are specifically incorporated and become part of the argument for the subsequent limitations as well.

**8. Dependent Claim 5: “further comprises a pH electrode that is external to the housing”**

181. Claim 5 depends from claim 1, and requires that the recited liquid chromatography system “further comprises a pH electrode that is external to the housing.”

182. I have discussed why this element is not met with respect to my discussion of element 1.e. and the last element discussed above for claim 1(m). I incorporate those discussions fully for this element. Therefore, the “pH electrode” is not “external to the housing” as required.

**9. Dependent Claim 6: “that the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve”**

183. Claim 6 depends from claim 5, and requires “that the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve.”

184. I have discussed why this element is not met with respect to my discussion of element 1.e. and the other elements of claim 1. All of the fluid handling modules in the Bio-Rad accused devices are structured in the same way as the pump and inject valves I discussed with claim 1 and cannot meet the elements of that claim for the same reasons. Further, as discussed above with regard to element 1(m) all of the sensor units or modules used in the Bio-Rad accused devices have the same general structure. In addition to the types of electronics identified for the fluid handling units, all the sensor units have further electronics outside the housing which are used to perform the sensing function.

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**10. Dependent Claim 7: “the pH electrode is connected to a pH valve formed as an interchangeable modular component”**

185. Claim 7 depends from claim 5, and requires that “the pH electrode is connected to a pH valve formed as an interchangeable modular component.”

186. For the reasons stated previously with respect to the claims discussed already, a pH valve with an electrode attached in the Bio-Rad accused products cannot infringe.

**11. Dependent Claim 8: “the pH valve includes an integrated flow cell for in-line monitoring of pH levels”**

187. Claim 8 depends from claim 7, and requires that “the pH valve includes an integrated flow cell for in-line monitoring of pH levels.” See claim 7.

**12. Dependent Claim 15: “the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve.”**

188. Claim 15 depends from claim 1, and requires “the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve.”

189. For the reasons stated previously with respect to the claims already discussed, any of these modules in the Bio-Rad system cannot meet the limitations of this claim. .

**13. Element [17.v]: “a panel member arranged to separate a fluidics section from a non-fluidics section”**

190. Element [17.v] of the ’420 patent requires “a panel member arranged to separate a fluidics section from a non-fluidics section.”

191. I have discussed why this element is not met with respect to my discussion of element 1(e) through 1.h. I incorporate those discussions fully for this element.

**14. Element [17.ix]: “wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when**

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**inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing”**

192. See corresponding element of claim 1 which I incorporate herein. Element

**15. Element [17.xi]: “wherein each interchange modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus”**

193. Element [17.xi] of the ’420 patent requires “each interchange modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus.”

194. I have discussed why this element is not met with respect to my discussion of element 1.k . I incorporate those discussions fully for this element.

195. In summary, a person of ordinary skill in the art would not read this limitation to mean that the “modular fluid handling unit” cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (e.g., A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

196. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

**16. Element [17.xiii]: “wherein said housing is adapted to accommodate at least one pump, at least one sensor unit, and at least two fluid control valves of different configurations, of which at least two of the**

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**pump, the sensor unit, and the fluid control valves are interchangeable modular components”**

197. Element [17.xiii] of the ’420 patent requires “said housing is adapted to accommodate at least one pump, at least one sensor unit, and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components”

198. I have discussed why this element is not met with respect to my discussion of element 1.k of the ’420 patent. I incorporate those discussions fully for this element.

**17. Dependent Claim 22**

199. *Claim 22* is analogous to dependent claim 5. *See* VII.A.8.

**18. Dependent Claim 23**

200. *Claim 23* is analogous to dependent claim 6. *See* VII.A.9.

**19. Dependent Claim 24**

201. *Claim 24* is analogous to dependent claim 7. *See* VII.A.10.

**20. Dependent Claim 25**

202. *Claim 25* is analogous to dependent claim 8. *See* VII.A.11.

**21. Element [27.e]: “a panel member arranged to separate a fluidics section from a non-fluidics section”**

203. Element [27.e] of the ’420 patent requires “a panel member arranged to separate a fluidics section from a non-fluidics section.”

204. I have discussed why this element is not met with respect to my discussion of element 1.h. I incorporate those discussions fully for this element.

205. The NGC System does not infringe this element because the NGC System does not include “a panel member arranged to separate the fluidics section from the non-fluidics section” as claimed. I incorporate my discussion of elements [1.e] and [1.f] for this element. In

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summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as embedded in the panel member. “Embedding” as shown with the arrangement of Bergstrom does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being embedded in the panel member are the fluidics in the Bio-Rad accused modules, which are not on “either side” of the panel member as the inventors said they must be. Ex. G at 1451 (“The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel.**”)(emphasis added).

**22. Element [27.i]: “wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing”**

206. Element [27.i] of the ’420 patent requires “wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing.”

207. I have discussed why this element is not met with respect to my discussion of elements 1(e), 1(f) and 1(h). I incorporate those discussions fully for this element.

208. The NGC System does not infringe this element because the alleged housing lacks the underlined portions of the claim element: “the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and

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adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing.”

209. In summary, the failure of proof for this element is most easily demonstrated with reference to the inventors’ discussion of the Hess reference. As discussed with respect to elements 1(e) and 1(f), in the Hess reference, each module had electronics sealed in a box and fluidics visible from a side that one can consider the front of the box. The inventors pointed out that what the examiner was considering the modules also had a single electrical connection exiting the back of the box. *See e.g.* ¶¶ 91-93 herein. For this reason, they concluded that Hess did not have a non fluidics section internal to said housing and a fluidics section external to said housing. There is no way for one of ordinary skill in the art to distinguish the arrangement in Hess that the inventors said was outside the scope of their invention with the arrangement in the accused modules. In the accused modules, there are electronics outside the housing. Those electronics cannot be a section that is distinct from the electronics that are inside the housing, just like the single electronic connection in Hess was not distinct from the electronics contained in the sealed boxes. Because the electronics inside the sealed boxes in Hess, that the examiner considered a housing did not constitute a non fluidics section that was internal to said housing when inserted, one of ordinary skill in the art could not also consider the electronics that Dr. Wereley considered to be embedded in the panel member to be a non fluidic section that is distinct from the electronics that are inside the housing in the Bio-Rad accused modules.

210. Therefore, Dr. Wereley has failed to meet his burden to establish the existence of this element in the accused fluid handling modules.

- 23. Element [27.k]: “wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus”**

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211. Element [27.k] of the ’420 patent requires “each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus.”

212. I have discussed why this element is not met with respect to my discussion of element 1.k of the ’420 patent. I incorporate those discussions fully for this element.

213. In summary, a person of ordinary skill in the art would not read this limitation to mean that the “modular fluid handling unit” cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

214. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

**24. Element [27.m]: “wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components”**

215. For the reasons stated previously the sample inject module and the two system pump modules are not interchangeable modular components because the interchangeable modular components of claim 1 need to have the fluidics and non fluidics sections of elements 1.e and 1.f as well as the separation requirements of elements 1 (h, i, j) and the independent

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operations requirements of element 1.k and identification requirement of 1(l) which the sample inject module and the two pump modules do not have as described previously which I incorporate herein.

216. In summary, with respect to the UV module that Dr. Wereley points relies on to satisfy this claim element, he identifies a sensor unit, but neither the Bio-Rad single or multi-wavelength UV detectors qualifies as interchangeable modular units that can satisfy this element because neither has the required fluidics and non fluidics sections, a panel member for separating those sections, and a liquid handling panel for separating those sections, nor does either satisfy the requirement that the electronics be internal to the housing when inserted.

217. One of ordinary skill in the art reading the file history, specification and claims would conclude that the Bio-Rad single and multi-wavelength detectors are not interchangeable modular units as required by the claims. In fact, the inventors addressed this very type of component and unequivocally stated that such a detector did not come within the claims of its invention.

**25. Dependent Claim 30: “the system further comprises a pH electrode that is external to the housing, and wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component”**

218. Claim 30 depends from claim 27, and requires that “the system further comprises a pH electrode that is external to the housing, and wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component.”

219. I have discussed why this element is not met with respect to my discussion of element 1.e and claim 5. I incorporate those discussions fully for this element. Therefore, the “pH electrode” is not “external to the housing” as required.

**B. Non-Infringement of the ’589 Patent**



**HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS’ EYES ONLY**

1. **Element [1.d]: “wherein the housing unit comprises on one external side of the housing unit a plurality of receiving positions, each receiving position adapted to receive the modular fluid handling units therein such that a fluid handling section thereof is on the external side of the housing unit, the receiving positions being arranged in a two dimensional array”**

220. Element [1.d]: “wherein the housing unit comprises on one external side of the housing unit a plurality of receiving positions, each receiving position adapted to receive the modular fluid handling units therein such that a fluid handling section thereof is on the external side of the housing unit, the receiving positions being arranged in a two dimensional array.”

221. I have discussed why there is not fluid handling section in the accused products with respect to claim 1 of the 420 patent which I incorporate fully herein.

2. **Element [1.g]: “wherein each modular fluid handling unit . . . includes a CPU for independently performing fluid control operations in response to instructions over a system BUS”**

222. Element [1.g] of the ’589 patent requires “wherein each modular fluid handling unit . . . includes a CPU for performing fluid control operations independently irrespective of the location within the housing unit.”

223. See discussion for corresponding element of claim 1 of the 420 patent incorporated herein.

3. **Element [6.f]: “each modular fluid handling unit includes a CPU for performing fluid control operations independently irrespective of the location within the housing unit”**

224. See corresponding element of claim 1 of the 420 patent incorporated herein.

4. **Dependent Claim 7: “housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are freely arrangeable modular fluid handling units”**

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225. Claim 7 depends from 6, and requires that the “housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are freely arrangeable modular fluid handling units.”

226. I have discussed why this element is not met with respect to my discussion of claim 1 and element 1.e and dependent claims 5-6 of the ’420 patent. I incorporate those discussions fully for this element.

**5. Dependent Claim 8: “housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit and the fluid control valves are arranged as modular fluid handling units”**

227. Claim 8 depends from 1, and requires that the “housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit and the fluid control valves are arranged as modular fluid handling units.”

228. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the ’420 patent. I incorporate those discussions fully for this element.

**6. Dependent Claim 9: “the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, and an outlet valve”**

229. Claim 9 depends from claim 8, which in turn depends from claim 1, and requires that “the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, and an outlet valve.”

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230. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the ’420 patent. I incorporate those discussions fully for this element.

**7. Dependent Claim 13: “the automatic liquid chromatography system further comprises a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit”**

231. Claim 13 depends from claim 1, and requires that “the automatic liquid chromatography system further comprises a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit.”

232. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the ’420 patent. I incorporate those discussions fully for this element.

**8. Dependent Claim 14: “the pH valve includes an integrated flow cell for in-line monitoring of pH levels”**

233. Claim 14 depends from claim 13, and requires that “the pH valve includes an integrated flow cell for in-line monitoring of pH levels.”

234. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the ’420 patent. I incorporate those discussions fully for this element.

**9. Dependent Claim 21: “the fluid handling section of the modular fluid handling unit is sealed from an internal side of the housing unit when fitted in a receiving position of the housing unit”**

235. Claim 21 depends from claim 20, and requires that “the fluid handling section of the modular fluid handling unit is sealed from an internal side of the housing unit when fitted in a receiving position of the housing unit.”

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236. I have discussed why this element is not met with respect to my discussion of element 1.h of the ’420 patent. I incorporate those discussions fully for this element.

237. The NGC System does not infringe this element because the NGC System does not include “a panel member arranged to separate the fluidics section from the non-fluidics section” as claimed. I incorporate my discussion of elements [1.e] and [1.f] for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as embedded in the panel member. “Embedding” as shown with the arrangement of Bergstrom does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being embedded in the panel member are the fluidics in the Bio-Rad accused modules, which are not on “either side” of the panel member as the inventors said they must be. Ex. G at 1451 (“The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel.**”)(emphasis added).

**10. Dependent Claim 24: “a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit”**

238. Claim 24 depends from claim 6, and requires “a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit.”

239.

**11. Dependent Claim 25: “the pH valve includes an integrated flow cell for in-line monitoring of pH levels”**

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240. Claim 24 depends from claim 24, which depends from claim 6, and requires “the pH valve includes an integrated flow cell for in-line monitoring of pH levels.”

241. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the ’420 patent. I incorporate those discussions fully for this element.

**12. Dependent Claim 26: “the modular fluid handling units include two double piston pumps, one injection valve for injecting a sample onto a column connecting a flow path of the liquid chromatography system, a UV monitor, and a mixer”**

242. Claim 26 depends from claim 6, and requires “the modular fluid handling units include two double piston pumps, one injection valve for injecting a sample onto a column connecting a flow path of the liquid chromatography system, a UV monitor, and a mixer.”

243. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the ’420 patent. I incorporate those discussions fully for this element.

**C. Non-Infringement of the ’590 Patent**

**1. Element [1.b]: “interchanging at least two of the interchangeable modular components in a housing unit comprising at least four component receiving positions arranged in a two dimensional array, so as to allow for modification of the liquid chromatography fluid flow path among the at least four interchangeable modular components”**

244. Dr. Wereley has not shown that this element was met. I understand that in order to infringe this claim, which is a method claim the steps claimed need to have been performed. Additionally, they need to have been performed in the United States and after the 590 patent issued on January 18, 2017. I see no such proof offered in Dr. Wereley’s report.

245. At paragraphs 491-507, Dr. Wereley states that he has seen videos of people changing modules. But he does not establish in his report where this alleged changing is

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occurring, and he does not establish the date on which the alleged changing occurred. Further he does not establish that the fluid flow path actually changed. I understand that this element requires that fluid be flowed through the system and that the path be different than the path that existed before the change. I do not see evidence of that in Dr. Wereley’s report.

246. Moreover, Dr. Wereley’s claim, citing testimony from Mr. Chapman at ¶ 501, that Bio-Rad changes the modules on customers machines approximately [REDACTED] of the time does not establish infringement of this element. First, the testimony from Mr. Chapman stated that he guessed changes were made in [REDACTED] of the occasions where he was present helping customers. That does not mean that Mr. Chapman is present at 100% of customer sites and thus his guess of [REDACTED] equates to [REDACTED] of Bio-Rad customers performing this operation. Second, Mr. Chapman did not testify that the times where he was present and customers made changes were done in the United States and after January 18, 2017. Last, Mr. Chapman did not testify that the fluid flow patent changed. Moving a module to a different position does not necessarily change the flow path. For example if one has two pump modules, module one can be placed where module 2 was, and a new pump can then be placed where module one was.

247. Additionally, Dr. Wereley cites as proof the fact that Discover machines are shipped with no modules in them and then are populated with modules. But placing a module in a machine with no modules does not satisfy the claim. Rather, modules must be taken out, and the flow path in situation one and situation two, (the interchanged modules) must be different. That is not possible when the first situation had no flow path at all because it had no modules.

2. **Element [1.c]: “wherein each of the at least four interchangeable modular components comprises a CPU unit for independently performing fluid control operations in response to instructions from a system controller when installed in a component receiving position of the housing unit”**

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248. Element [1.c] of the ’590 patent requires “wherein each of the at least four interchangeable modular components comprises a CPU unit for independently performing fluid control operations in response to instructions from a system controller when installed in a component receiving position of the housing unit.”

249. The NGC System does not infringe claim 1 of the ’590 patent because it lacks “at least four interchangeable modular components comprises a CPU unit for independently performing fluid control operations in response to instructions from a system controller when installed in a component receiving position of the housing unit.”

250. I have discussed why this element is not met with respect to my discussion of elements 1.k of the ’420 patent. I incorporate those discussions fully for this element.

251. In summary, a person of ordinary skill in the art would not read this limitation to mean that the “modular fluid handling unit” cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

252. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

**3. Claims 2 and 3, Flow path shortened**

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253. None of the evidence that Dr. Wereley cited shows that even if modules are interchanged, the flow path is shortened. The same is true for the evidence he cited for claim 3. Thus, he failed to meet his burden on these claims.

**4. Claims 10 and 12**

254. Dr. Wereley has not met his burden to establish infringement of these claims. While he says the steps claimed could be done, he points to nothing where these steps were actually done in the United States after Jan. 18, 2017. That is what is necessary to establish infringement of this method claim. For this reason, he has not met his burden to show infringement.

**5. Element [13.h]: “comprising a CPU that allows independent fluid control operations in response to instructions from the main controller when installed in the component receiving position of the housing unit”**

255. Element [13.h] requires “the at least two interchangeable modular fluid handling units ... compris[e] a CPU that allows independent fluid control operations in response to instructions from the main controller when installed in the component receiving position of the housing unit”

256. I have discussed why this element is not met with respect to my discussion of element 1.k of the ’420 patent. I incorporate those discussions fully for this element.

257. In summary, a person of ordinary skill in the art would not read this limitation to mean that the modular component’s cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.



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258. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

- 6. Claim 14 “adding an expansion housing unit that includes a plurality of component receiving positions, each component receiving position being adapted to receive the at least one interchangeable modular fluid handling unit, and placing at least one additional interchangeable modular fluid handling unit in one of the component receiving positions in the expansion housing”**

259. While Dr. Wereley states that the elements of these claims could be done, he does not cite evidence showing that the expansion housings were used. Nor does he show any use in the United States after January 18, 2017. He has therefore failed to meet his burden to establish infringement.

- 7. Claim 17: “the CPU allows for automatic identification by the liquid chromatography system upon placement in a component receiving position of similar size and shape”**

260. I do not agree with Dr. Wereley that the CPU does need to do the identification. In any event, the testimony that Dr. Wereley cites and his conclusion about infringement of this claim are inconsistent with the conclusions he reached in corresponding claims of the 420 patent where he stated that the MCU was doing the identification. I incorporated the arguments I made with respect to that claim. Moreover as with the other claims in this patent he has not shown that the method was actually performed in the U.S. at the proper time.

- 8. Claim 18: “the at least two interchangeable modular fluid handling units are connected to the system by a system BUS”**

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261. Dr. Wereley has not provided any evidence showing that this step was performed in the U.S. at the proper time to establish infringement. Therefore he has failed to meet his burden of proof.

**D. The ’591 Patent**

**1. The NGC System Does Not Infringe Claim 9 of the ’591 Patent at Least Because it Lacks Several Elements in Claim 1 from Which it Depends**

262. Claim 9 depends on claim 1. I note that claim 1 of the ’591 patent is nearly identical to claim 1 of the ’420 patent. Thus, I incorporate my analysis of claim 1 of the ’420 patent.

**(a) Element [1.v]: an external fluidics section**

263. Element [1.v] requires “an external fluidics section.”

264. I have discussed why this element is not met with respect to my discussion of element 1.e of the ’420 patent. I incorporate those discussions fully for this element.

**(b) Element [1.vi]: an internal non fluidics section**

265. I have discussed why this element is not met with respect to my discussion of element 1.f of the ’420 patent. I incorporate those discussions fully for this element.

**(c) Element [1.viii]: “a panel member arranged to separate the fluidics section from the non-fluidics section”**

266. Element [1.viii] of claim 1 of the ’591 patent requires “a panel member arranged to separate the fluidics section from the non-fluidics section.”

267. The NGC System does not infringe claim 9 at least because it lacks “a panel member arranged to separate the fluidics section from the non-fluidics section,” as claimed.

268. I have discussed why this element is not met with respect to my discussion of element 1.h of the ’420 patent. I incorporate those discussions fully for this element.

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269. The NGC System does not infringe this element because the NGC System does not include “a panel member arranged to separate the fluidics section from the non-fluidics section” as claimed. I incorporate my discussion of elements [1.e] and [1.f] of the ’420 patent for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as embedded in the panel member. “Embedding” as shown with the arrangement of Bergstrom does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being embedded in the panel member are the fluidics in the Bio-Rad accused modules, which are not on “either side” of the panel member as the inventors said they must be. Ex. G at 1451 (“The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel.**”)(emphasis added).

**(d) Element [1.ix]: “wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing”**

270. Element [1.ix] of claim 1 of the ’591 patent requires “wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing.”

271. The NGC System does not infringe claim 9 at least because it lacks “wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the

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fluidics section is external to the housing and the non-fluidics section is internal to the housing,” as claimed.

272. I have discussed why this element is not met with respect to my discussion of elements 1.e and 1.f of the ’420 patent. I incorporate those discussions fully for this element.

**(e) Claim [1.xi]: “wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus”**

273. Dependent claim [1.xi] requires “wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus.”

274. The NGC System does not infringe claim 9 at least because it lacks “wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus,” as claimed.

275. I have discussed why this element is not met with respect to my discussion of element 1.k of the ’420 patent. I incorporate those discussions fully for this element.

276. In summary, a person of ordinary skill in the art would not read this limitation to mean that the modular component’s cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

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277. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

**2. Dependent Claim 26: “the pH electrode is connected to a pH valve formed as an interchangeable modular component”**

278. Claim 26 depends from claim 12, and recites that “the pH electrode is connected to a pH valve formed as an interchangeable modular component.”

279. I have discussed why this element is not met with respect to my discussion of element 1.e of the ’420 patent. I incorporate those discussions fully for this element.

**3. Dependent Claim 27: “the pH valve include[] an integrated flow cell for in-line monitoring of pH levels”**

280. Claim 27 depends from claim 26, and further requires that “the pH valve include[] an integrated flow cell for in-line monitoring of pH levels.”

281. I have discussed why this element is not met with respect to my discussion of element 1.e of the ’420 patent. I incorporate those discussions fully for this element.

**E. Non-Infringement of the ’124 Patent**

**1. Element [16.h]: “a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel.”**

282. Element [16.h] requires “a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel.”

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283. The NGC System does not infringe claim 16 at least because it lacks “a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel,” as claimed.

284. I have discussed why this element is not met with respect to my discussion of element 1.h of the ’420 patent. I incorporate those discussions fully for this element.

285. The NGC System does not infringe this element because the NGC System does not include “a panel member arranged to separate the fluidics section from the non-fluidics section” as claimed. I incorporate my discussion of elements [1.e] and [1.f] of the ’420 patent for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as embedded in the panel member.

“Embedding” as shown with the arrangement of Bergstrom does not create separate sections.

There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being embedded in the panel member are the fluidics in the Bio-Rad accused modules, which are not on “either side” of the panel member as the inventors said they must be. Ex. G at 1451 (“The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel.**”)(emphasis added).

**2. Element [16.i]: “wherein the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing”**

286. Element [16.i] requires “wherein the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing.”

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287. The NGC System does not infringe claim 16 at least because it lacks “the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing” as claimed.

288. I have discussed why this element is not met with respect to my discussion of elements 1.e and 1.f of the ’420 patent. I incorporate those discussions fully for this element.

**3. Element [16.j]: “respective non fluidics sections are internal to the housing”**

289. Element [16.j] requires that the “respective non fluidics sections are internal to the housing.”

290. I have discussed why this element is not met with respect to my discussion of element 1.f of the ’420 patent. I incorporate those discussions fully for this element.

**4. Dependent Claim 20: “wherein each of the interchangeable modular components includes a dedicated CPU unit allowing each of the interchangeable modular components to independently perform operations in response to instructions over the bus”**

291. Element [20.c] requires “wherein each of the interchangeable modular components includes a dedicated CPU unit allowing each of the interchangeable modular components to independently perform operations in response to instructions over the bus.”

292. The NGC System does not infringe Claim 20 at least because it lacks “wherein each of the interchangeable modular components includes a dedicated CPU unit allowing each of the interchangeable modular components to independently perform operations in response to instructions over the bus” as claimed.

293. I have discussed why this element is not met with respect to my discussion of element 1.k of the ’420 patent. I incorporate those discussions fully for this element.

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294. In summary, a person of ordinary skill in the art would not read this limitation to mean that the modular component’s cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

295. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

**5. Dependent Claim 28 “the system includes two double piston pumps, one injection valve for injecting sample onto a column connecting to the flow path of the liquid chromatography system, a UV monitor, and a mixer”**

296. Claim 28 depends from claim 16, and further requires that the system recited there comprise “two double piston pumps, one injection valve for injecting sample onto a column connecting to the flow path of the liquid chromatography system, a UV monitor, and a mixer.”

297. I have discussed why this element is not met with respect to my discussion of element 1.e of the ’420 patent. I incorporate those discussions fully for this element.

**6. Dependent Claim 30: “further includes a pH-valve with an integrated flow cell for in-line monitoring of pH levels, and a quaternary valve for automatic buffer preparation and formation of quaternary gradients”**

298. Claim 30 depends from claim 28, which in turn depends on claim 16, and requires that the system “further includes a pH-valve with an integrated flow cell for in-line monitoring of



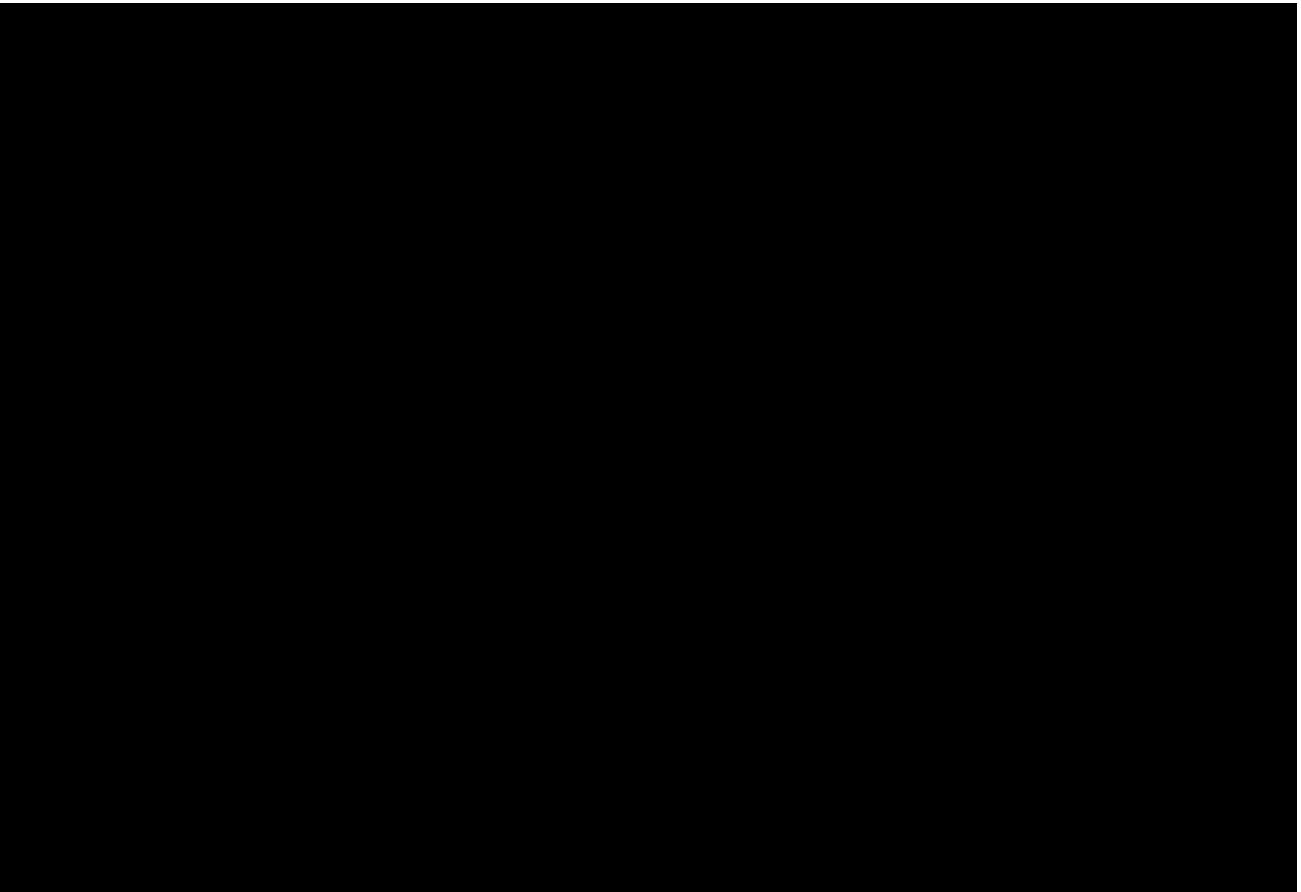
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pH levels, and a quaternary valve for automatic buffer preparation and formation of quaternary gradients.”

299. I have discussed why this element is not met with respect to my discussion of element 1.e of the ’420 patent. I incorporate those discussions fully for this element.

**IX. NON-INFRINGEMENT ALTERNATIVES**

300. I have also been asked to opine on the existence of non-infringing alternatives and the relative difficult in creating a non infringing alternative by modifying the accused NGC products. In summary, it is my opinion that non-infringing alternatives, such as the Bio-Rad DuoFlow, exist. That chromatography system was the predecessor to the NGC. Moreover, modifications to the NGC could be designed which would avoid infringement.



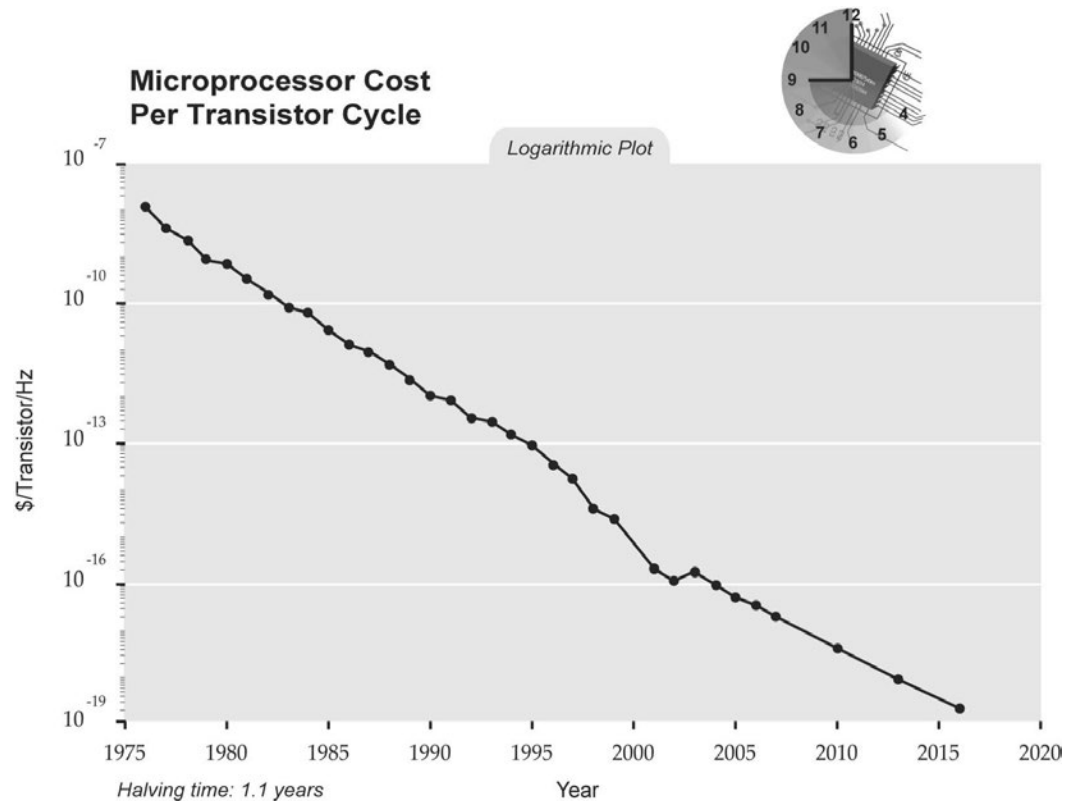
302. In this regard, Dr. Wereley has his analysis backwards. He states that not having a CPU on each module would result in increased cost and complexity and it is not clear that it

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would work. Wereley at ¶ 686. This is certainly not the case. One of ordinary skill in the art would recognize that when CPUs were more expensive and one was trying to keep the costs down, multiple CPUs were shared between interchangeable fluid handling modules. This is evident from the Applikon 2040 which was designed in the late 1990s when CPUs were more expensive than 10 years later when the asserted patents were filed. The Applikon 2040 directly refutes Dr. Wereley’s claim that it would be more expensive to have a shared CPU than it would be to have a CPU on every module.

303. Based on published data, the cost of a microprocessor decreased by between a hundred and a thousand-fold in the ten years between the late 1990s and the 2009 time frame when the asserted patents were filed. The chart published at the following site <http://www.singularity.com/charts/page62.html>, shows that cost per transistor from 1998 to approximately 2009 decreased by about one thousand fold. This would equate to a significant drop in the cost of a CPU required to perform any significant number of instructions.

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304.

305. Second, it is well understood in the engineering world that a CPU is a general purpose device that can be programmed over and over to perform multiple different operations. A CPU carries out operations in response to instructions which generally exist as source code. When one changes the source code, which can also be referred to as reprogramming it, they change the operations of the CPU. Because of the way a CPU operates, there are basic components that one of skill in the art would understand are present in a CPU, such as an Arithmetic Logic Unit (ALU), that performs among other things arithmetic and logic operations, registers for storing values, and other memory for storing programs or other operational values.

306.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

309. These non-infringing alternatives for the CPUs apply to all asserted independent claims except for ‘124 patent claim 16, and also to dependent ‘124 patent claim 20.

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310. Dr. Wereley again resorts to a misinterpretation of the Court’s claim construction order and fails to account for representations in the file history, when he claims that a rearrangement of the connections of each module to the system bus would not result in a non-infringing alternative. As I discussed previously with respect to the elements relating to fluidics sections, non fluidic sections, and the separation of the same by the panel member and the liquid handling panel, the inventors unequivocally stated with respect to the Hess reference that when you have an electrical connection for a module to other modules or the system bus outside the housing, that is not the claimed invention. See File History (Claim Construction Ex. G) at 1416 (“So by process of elimination, bus connections [in Hess] have to be at the back of the boxes – there is no other place for them, if the boxes are stackable and fit side by side as illustrated. This means that the bus connections cannot be internal to said boxes or internal to any ‘housing’. On the contrary, the bus connections must be external to said boxes to make sense of the description. Therefore, in Hess, *respective non fluidics sections are not internal to any housing as claimed.*”)

311. By ignoring this very unequivocal statement, Dr. Wereley, by the mere waving of his hand, calls any non fluidic component which is not consistent with the claim, part of a separate section. But, the inventor’s representations make it clear that one cannot do that. The external electrical connections, such as those to the bus are part of the non fluidics section as a whole. If they were not, then the way the inventors distinguished Hess would be meaningless. One could just as easily call the electrical connection on the back of the box, which is quite distant from the fluidic components, much more distant than the electrical components such as LEDs and the displays in the accused products, part of a separate non fluidic section. The inventors made it clear that was not allowable. The electrical connection at the back of the

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modules were part of the same non fluidic section as the electrical components contained inside the housing in Hess. When these representations are considered, the design around that Bio-Rad proposed is a non-infringing alternative. [REDACTED]

[REDACTED]. This configuration would be the same that the inventors said with regard to Hess did not qualify as their invention.

312. This non-infringing alternatives for the bus connectors applies to all asserted independent claims except for claim 6 of the ’589 patent and claims 1 and 13 of the ’590 patent.

313. [REDACTED]

[REDACTED]. That was actually one of the reasons that Cytiva’s predecessor decided to update the prior generation AKTA machines. Ex. 28, Hareland Depo Tr. at 75-77. That would be a relatively simple task. Last, if one wanted to make the DuoFlow more cosmetically pleasing, a cabinet could be built around the individual modules to make them look more like an integrated system. This would be akin to building a cabinet around your separate stereo components to make them look more like a single system.

**X. LICENSES**

314. I understand that, to be relevant to the assessment of damages in a patent case, a license must be technologically and economically comparable to a hypothetical license between the parties to the patents-in-suit. I have been asked to assess the technological comparability of

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the licenses produced by Bio-Rad, and one license produced by Cytiva, in this litigation. As part of my assessment, I have evaluated at least the following four factors: Similarities and differences between the patent claims and their scope, the manner in which the claimed inventions are implemented and the value of the inventions to the parties’ business, the differences between the claimed inventions and other known means of achieving the same operational goals or benefits, and the relative value of other, non-patented features of the products into which the claimed inventions may be incorporated. In making my assessment, I have considered the embodiments described in the licensed patents as well as their claims.

315. I further understand that there are other aspects of license comparability that are not technological in nature. Among these are things such as license structure and the economic circumstances of the parties. I have not been asked to offer and I am not offering any opinions, or any analysis directed toward any non-technological aspects of comparability.

316. It has been explained to me that, to assist the finder of fact, a determination must be made as to whether licensed technology is sufficiently comparable to the hypothetical license at issue in suit. When relying on licenses to prove a reasonable royalty, alleging a loose comparability between different technologies or licenses does not suffice. I have been informed that the analysis does involve an element of approximation and uncertainty, but in order to be technologically comparable the technologies of the patents being considered must not be substantially different.

317. I reviewed evidence regarding all of the license agreements that I understand Dr. Kearl is relying on as comparable licenses in relation to determining a reasonable royalty. Based on my review, it is my opinion that the licenses he relies on cover patents that are technologically

**HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS’ EYES ONLY**

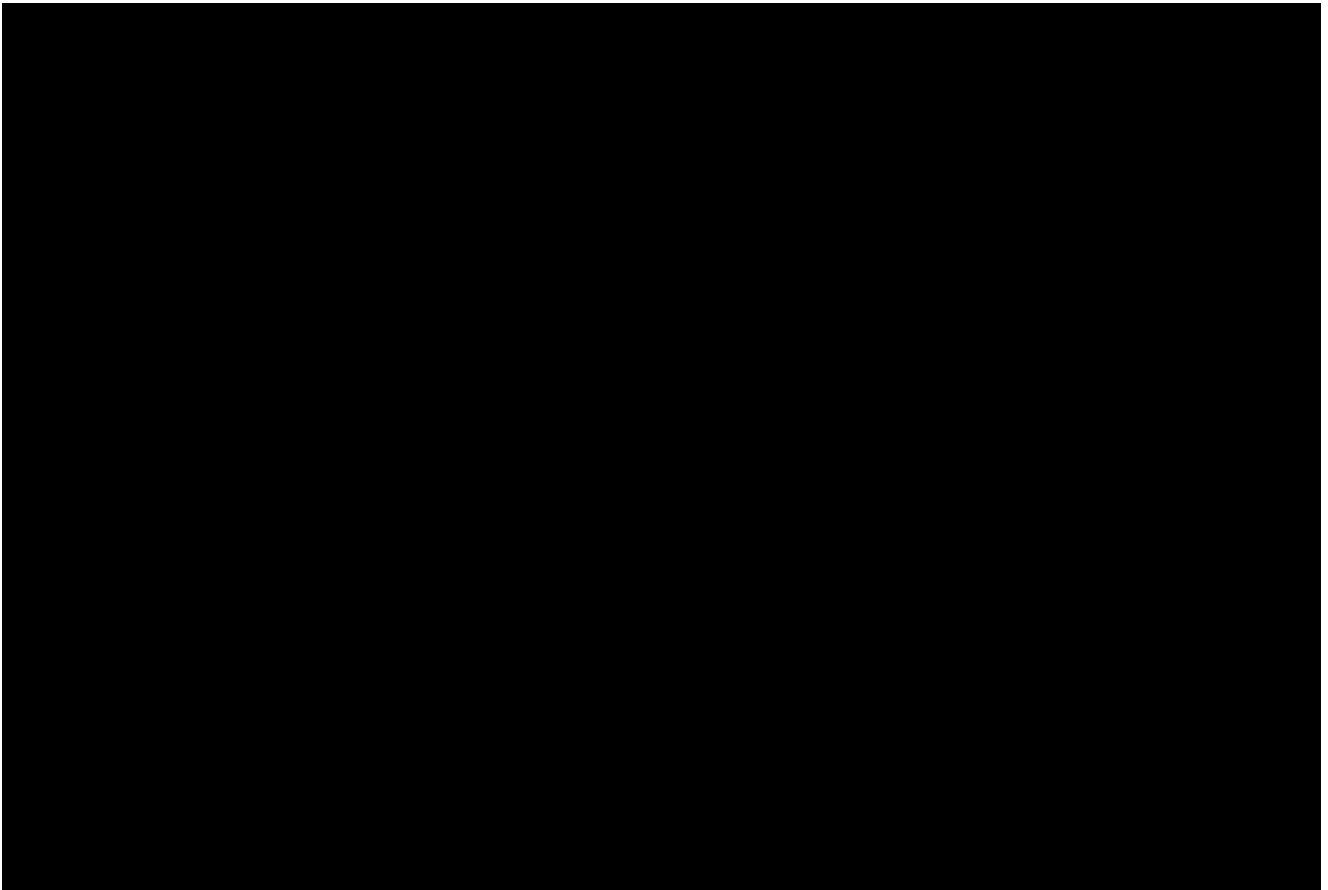
comparable and in some cases more advanced than the technology covered by the asserted patents.

A. 

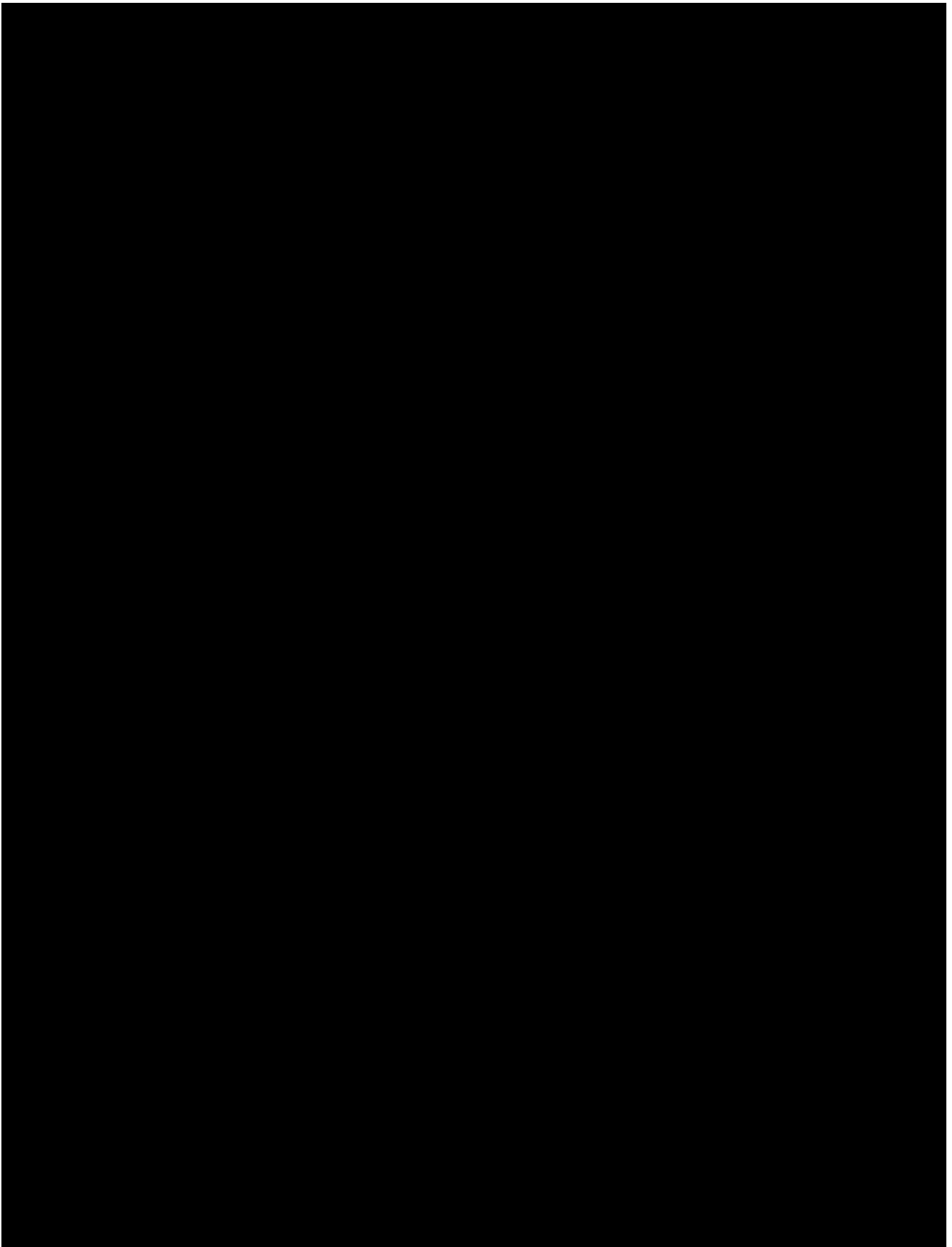




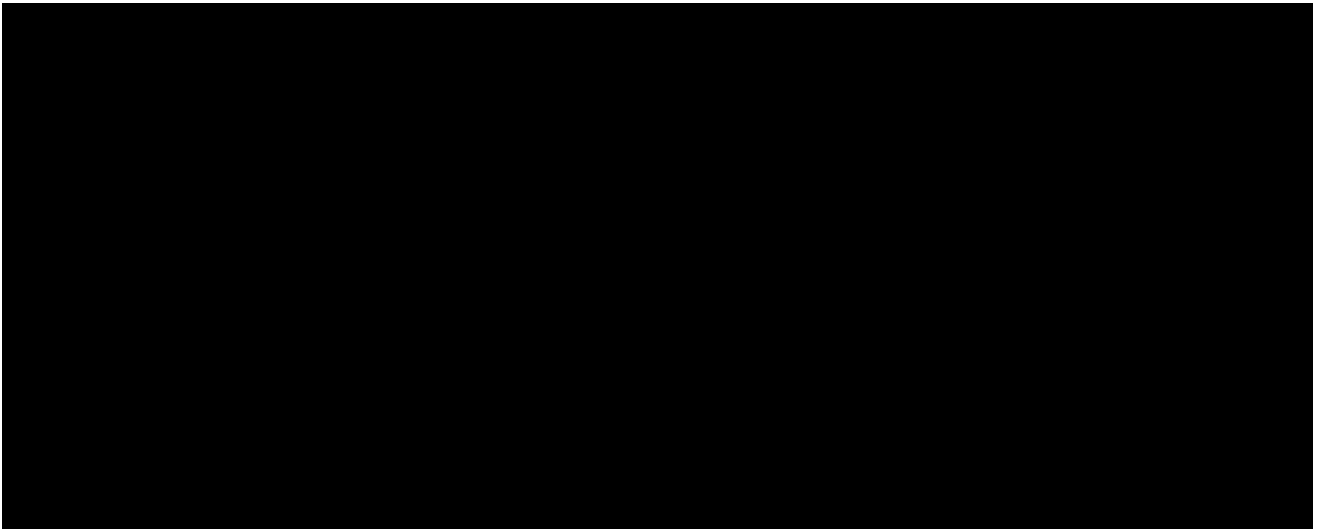
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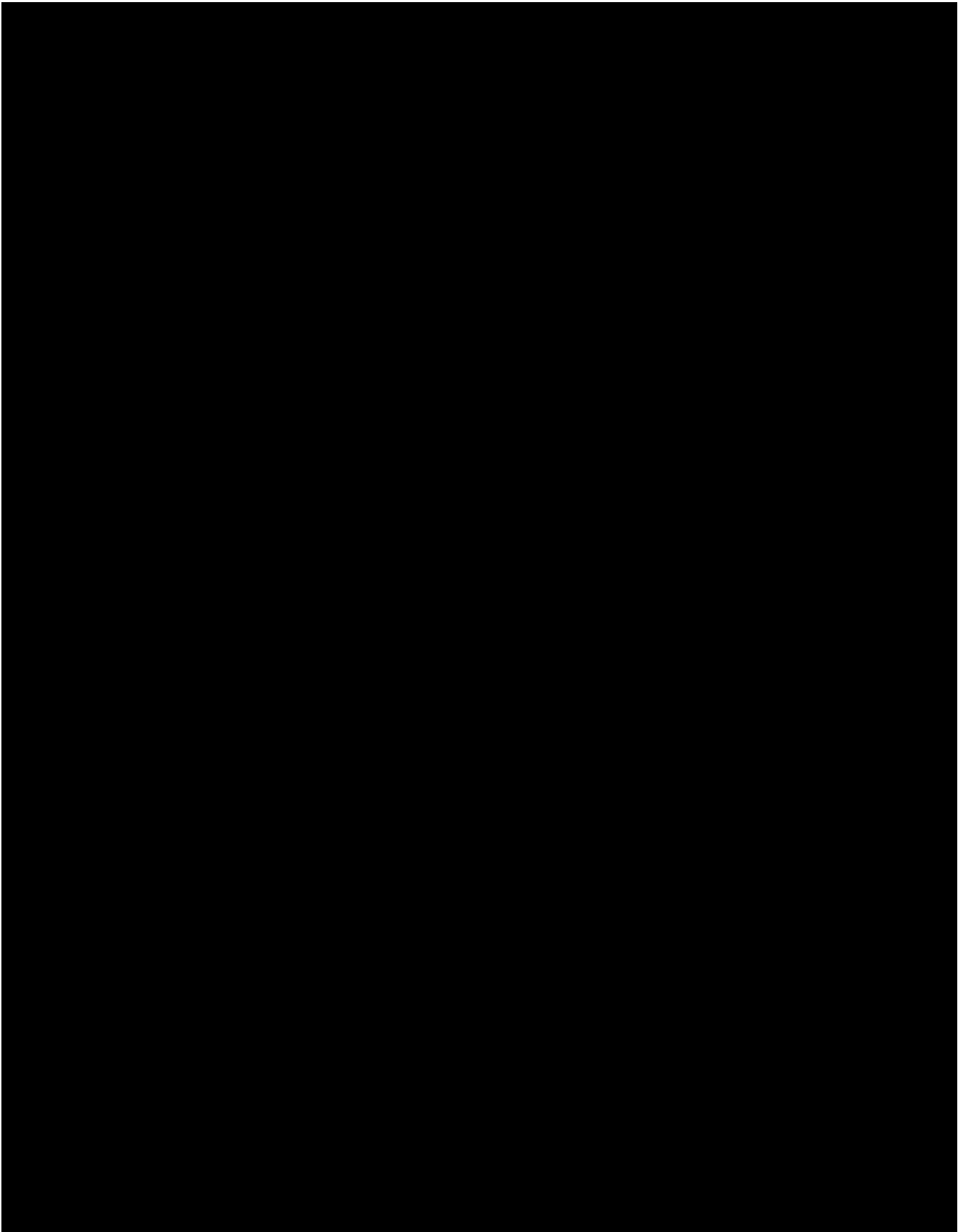
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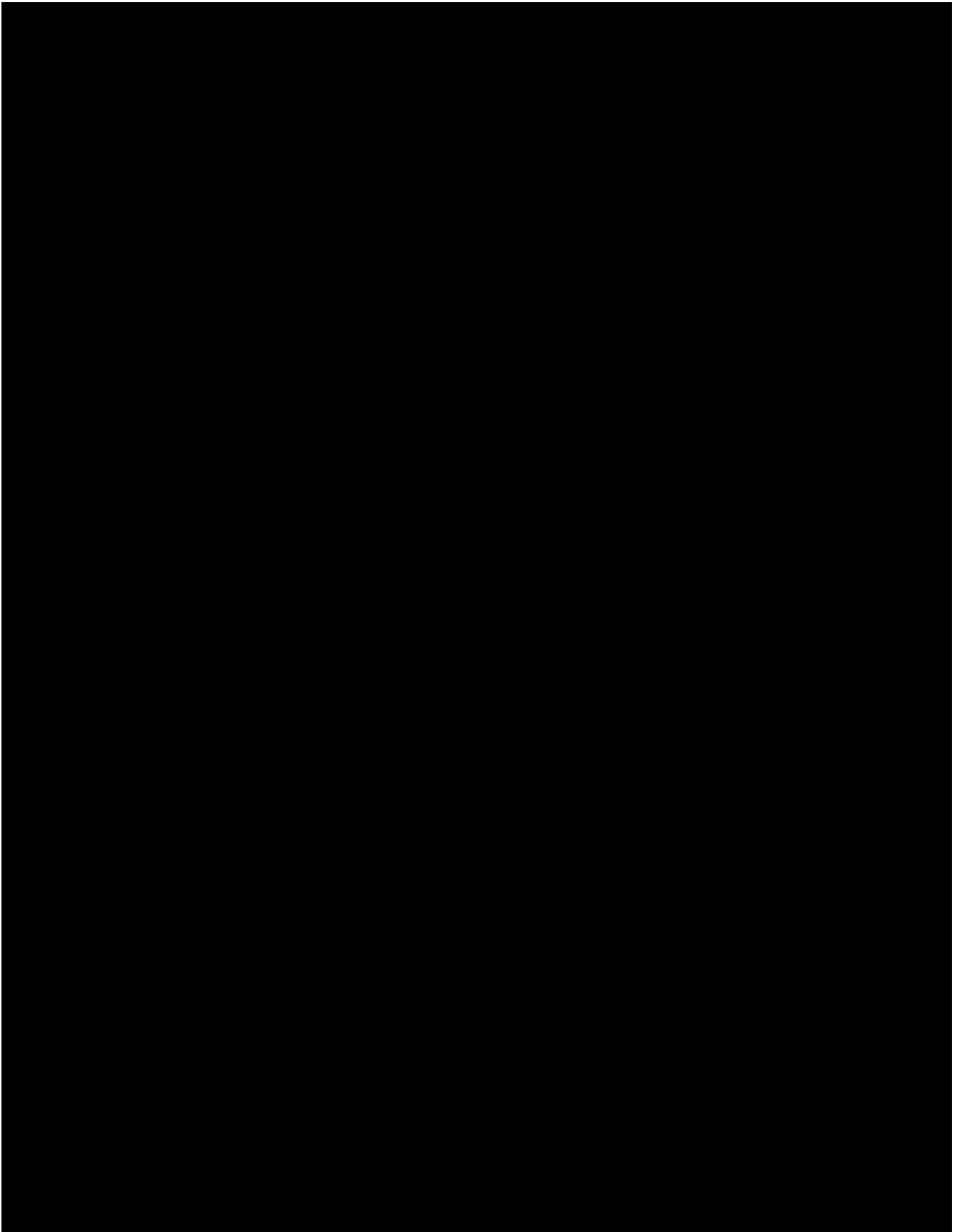
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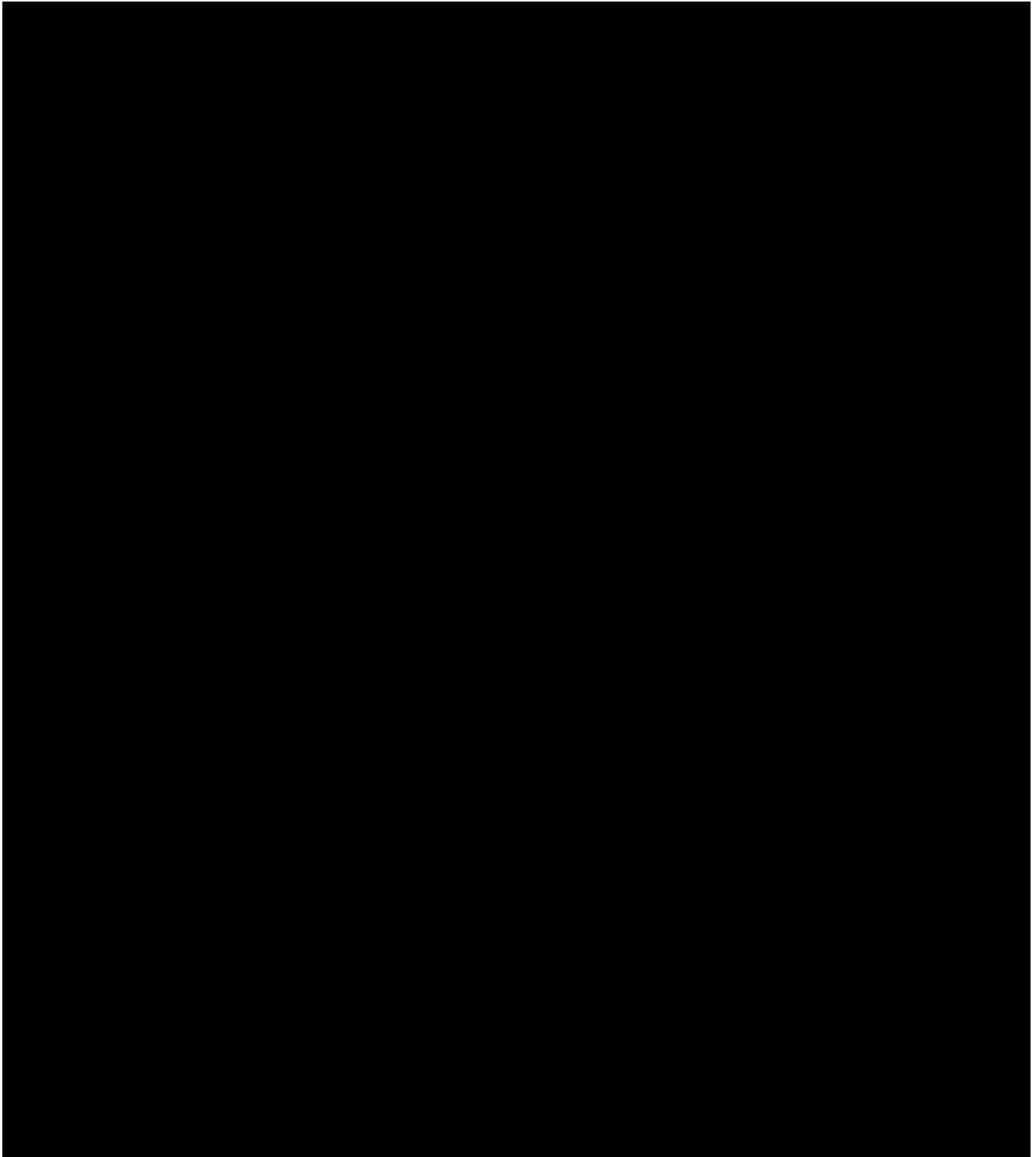
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**B.**

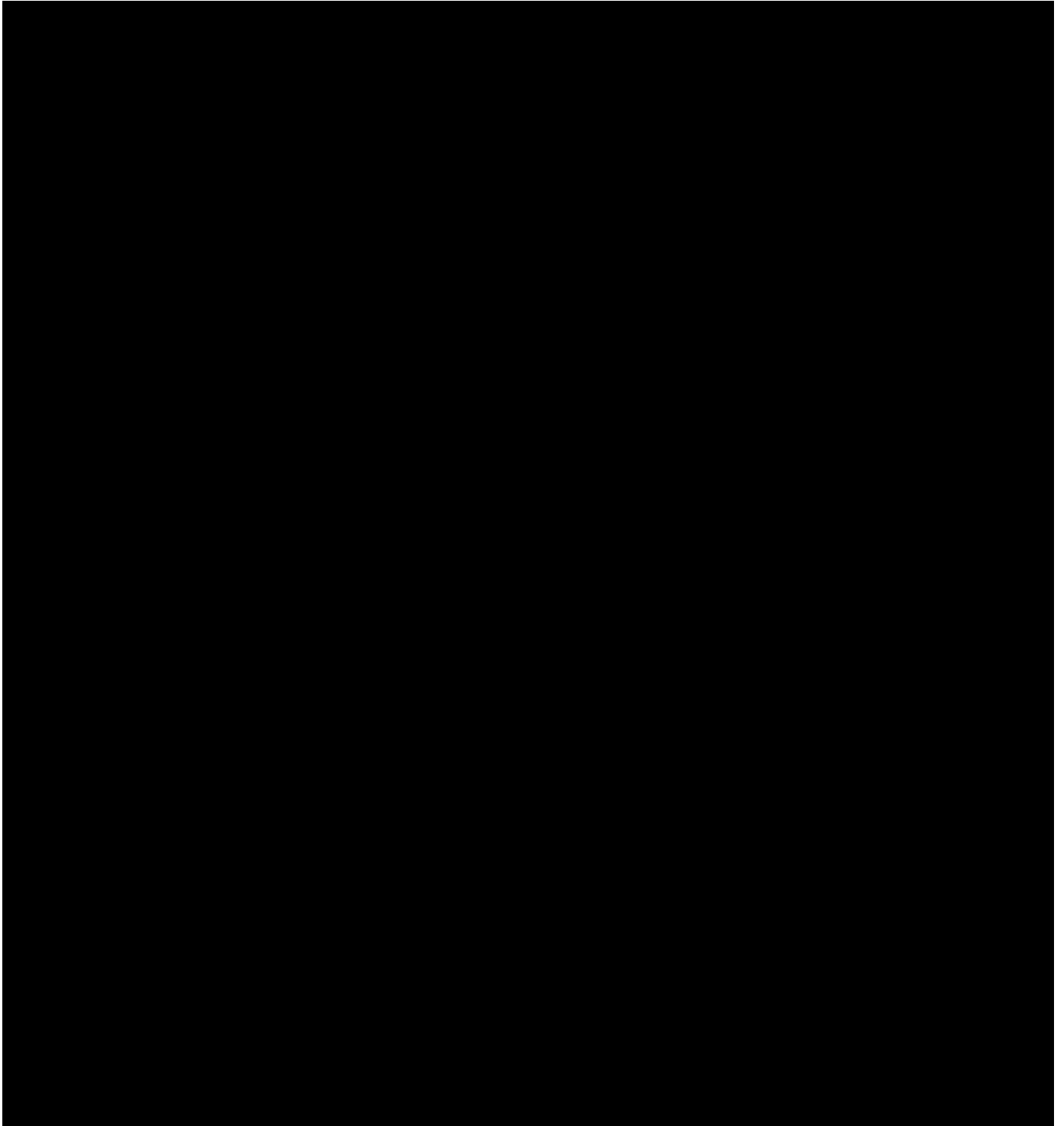
[REDACTED]

[REDACTED]

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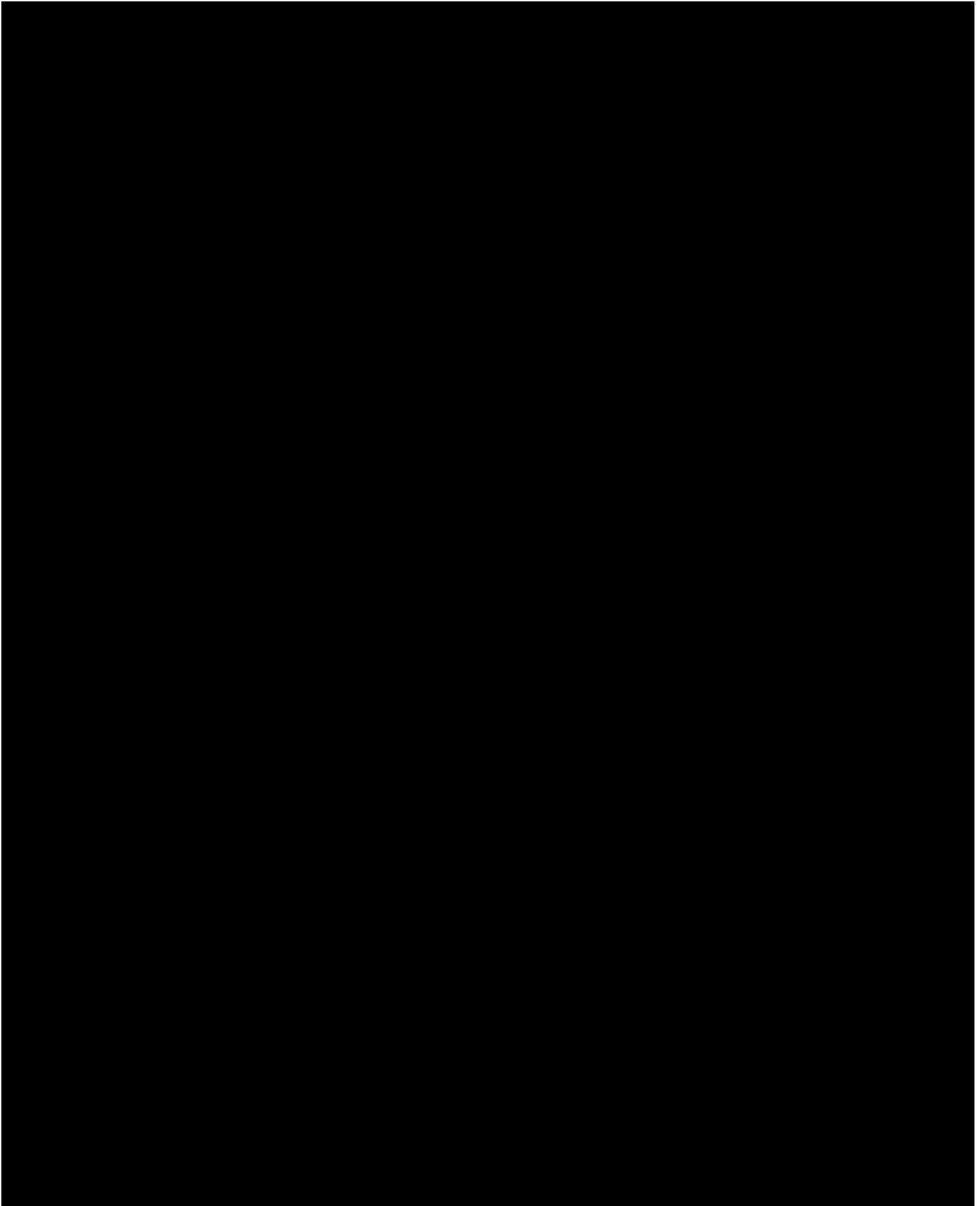


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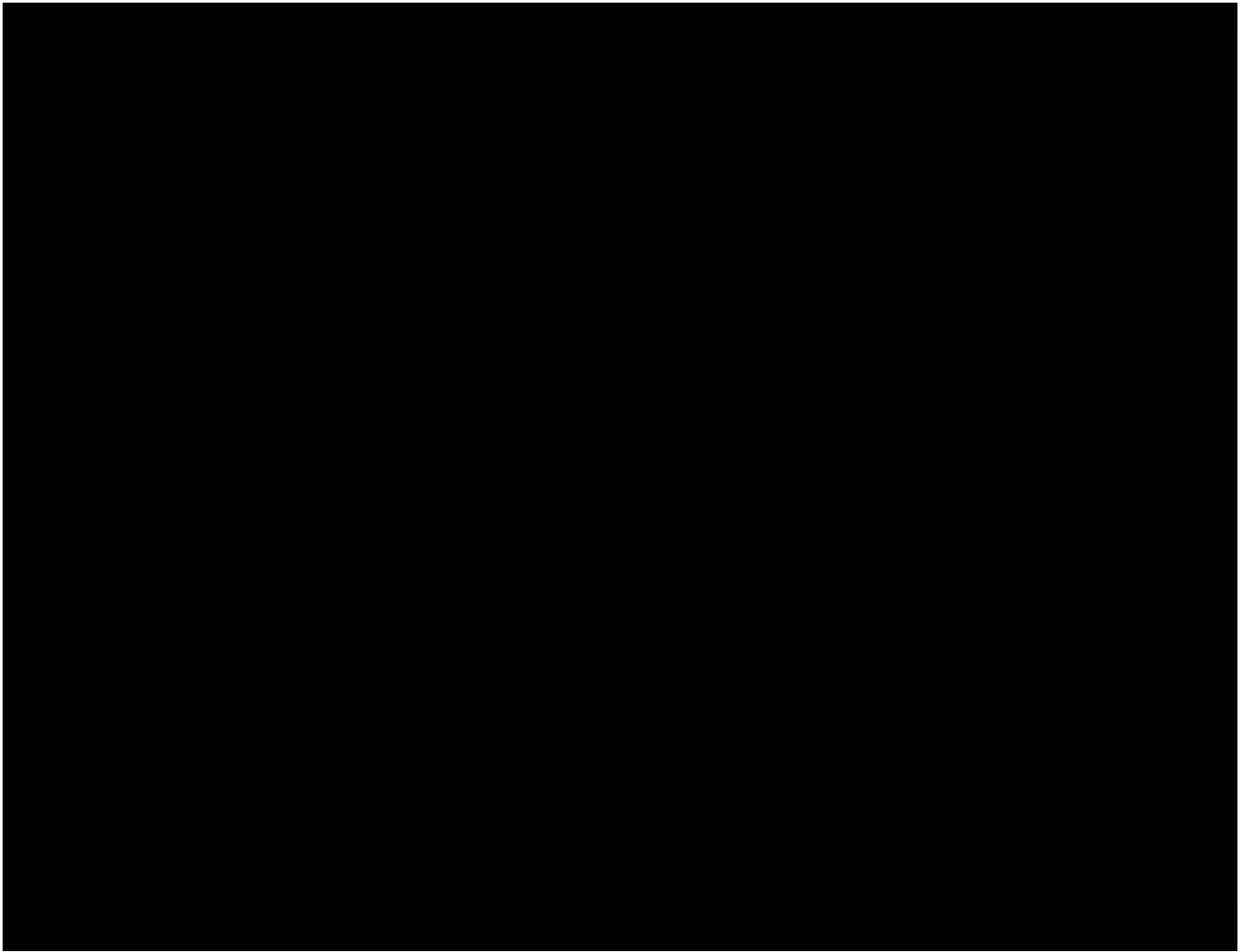




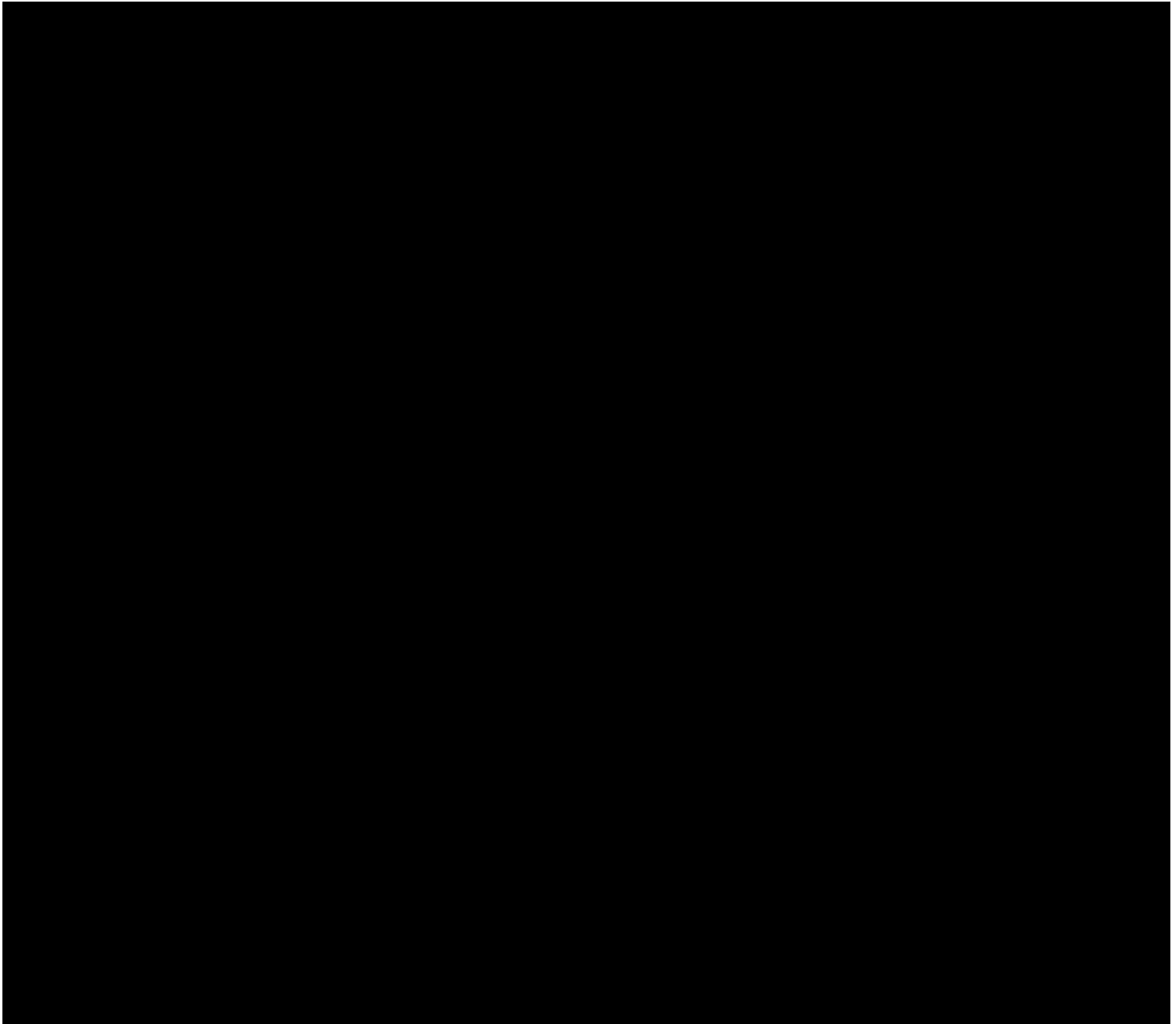
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**HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS’ EYES ONLY**



**HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS’ EYES ONLY**



**XI. OTHER COMMENTS**

348. The opinions expressed in this report are my preliminary opinions based on my review to date of the evidence produced at this stage of the case. I reserve the right to amend or supplement my opinions in light of additional information or materials that may be provided to me or that are relied upon by any of Plaintiffs’ experts or witnesses, as well as opinions that Plaintiffs’ experts or witnesses may present. I reserve my right to amend or update my opinions

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as appropriate in response to any future developments. With this in mind, based on the analysis I have conducted and for the reasons set forth below, I have preliminarily reached the conclusions and opinions in this report.

349. At a hearing or at trial I may use as exhibits various documents produced in this case that refer or relate to the matters discussed in this report. I have not yet selected the particular exhibits that might be used. I may also rely on visual aids and may rely on analogies concerning elements of the patents discussed above, Plaintiffs’ alleged practicing products, the accused products, the references cited in this report, or any related technologies. In addition, I may create or assist in the creation of certain demonstrative evidence to assist me in testifying, and I reserve the right to do so, such as demonstrations of devices and software to further support the positions in this report.

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DATED: October 21, 2020

  
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Bruce K. Gale, Ph.D.